UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CLEVELAND BAKERS AND TEAMSTERS HEALTH & WELFARE FUND, individually and behalf of all others similarly situated,

Plaintiff

v.

AMAG PHARMACEUTICALS, INC. and COVIS GROUP S.À R.L.,

Defendants.

Civil Action No. _____

Class Action

Jury Trial Demanded

COMPLAINT AND JURY DEMAND

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Plaintiff Cleveland Bakers and Teamsters Health & Welfare Fund ("Plaintiff") brings this proposed class action against AMAG Pharmaceuticals, Inc. ("AMAG") and Covis Group S.à r.l. ("Covis"), individually and on behalf of all others similarly situated, upon personal knowledge as to Plaintiff's own conduct, and on information and belief as to all other matters based on investigation by counsel.

I. NATURE OF THE ACTION

1. This civil action alleges AMAG Pharmaceuticals, a Waltham-based specialty drug company, and Covis Group S.à r.l., the Luxembourg-based pharmaceutical company that owns and controls AMAG, unlawfully marketed and sold the drug Makena in the United States knowing that the scientifically reliable, clinically meaningful evidence affirmatively showed the drug was ineffective for its ostensible use, reducing the risk of recurrent preterm birth.

2. In the United States, approximately one in ten babies is born prematurely. These babies face significant health problems and longer hospital stays than babies carried to term. Between 2011 and 2021, the preterm birth rate in the United States ranged from 9.6% to a high of 10.5%. The consequences can be grave: preterm birth accounted for 16% of infant deaths in 2020, and babies who survive may have respiratory problems, feeding difficulties, cerebral palsy, developmental delays, and vision and hearing impairment.

3. In 2011, Makena received "accelerated approval" from the FDA, a type of conditional approval based on preliminary evidence showing it reasonably likely to predict clinical benefit from the product; such approvals are conditioned on the applicant conducting well-controlled, post-marketing clinical studies to prove clinical effectiveness and safety. Makena was allowed to be marketed in the United States to prevent preterm birth in at-risk patients based on a controversial 2003 study (the "Meis Study") that ostensibly showed reduced risk of recurrent preterm birth prior to 37 weeks, a surrogate endpoint that FDA considered

reasonably likely to predict clinical benefit to the neonate. The approval of Makena was expressly conditioned on the results of a confirmatory clinical trial demonstrating that the drug was safe and effective. That trial, known as Progestin's Role in Optimizing Neonatal Gestation (the "PROLONG Study"), was sponsored by AMAG, the owner of the marketing rights to Makena, and thus AMAG had control of and authority over the study. The authors of the PROLONG Study included AMAG employees.

4. From 2011 through 2019, AMAG aggressively marketed Makena throughout the United States for the reduction of risk of recurrent preterm birth. While proof of the potential utility of Makena remained the subject of the mandatory follow-up study that was still underway, AMAG treated the drug, and the representations it made about it, as already proven. AMAG constructed an elaborate network of pharmaceutical marketing companies, doctors, and professional associations to maximize sales of Makena. AMAG's goal was clear: to supercharge its sales of Makena, which accounted for over sixty percent of the company's revenue. AMAG's marketing efforts targeted every participant in the healthcare system. They told expectant mothers that Makena was the best way for them to give their babies time to develop. They told physicians that Makena was the best treatment for patients with a history of preterm delivery. They prevailed on professional associations to make Makena the standard of care for at-risk patients. AMAG charged eye-popping prices for the only FDA-approved drug to prevent preterm birth. A single dose could cost upwards of $1,500. And a course of treatment, which could last from the sixteenth to the thirty-seventh week of pregnancy, could cost tens of thousands of dollars.

5. Over these eight years, AMAG slowly progressed with the PROLONG Study. AMAG was in a unique position to know that ongoing reports were continuing to show that

Makena was not effective at preventing preterm birth. Through its elaborate marketing efforts, AMAG maintained a direct connection with patients prescribed Makena, who informed the company that, despite paying hundreds or thousands of dollars for a drug with significant side effects, they nonetheless delivered their babies preterm. And as the sponsor of the PROLONG Study, AMAG and its employees also had inside knowledge about the study's ongoing progress and results.

6. In March 2019, the topline results of the PROLONG Study were, at long last, issued: Makena was no different than a placebo for the two primary endpoints studied (incidence of preterm delivery and the prespecified neonatal morbidity and mortality composite index). Months later the results of the study were published.

7. On October 29, 2019—only days after the final publication—the FDA concluded that the PROLONG Study "did not verify Makena's efficacy on obstetrical or neonatal outcomes."

8. So, by the fall of 2019, AMAG knew (i) that the scientifically reliable, clinically meaningful evidence affirmatively showed Makena was ineffective at reducing the risk of recurrent preterm birth and the effects of preterm birth, (ii) that the aggressive marketing campaign AMAG had waged for eight years had falsely told pregnant women, obstetricians, payors, and others in the healthcare community that Makena reduced the risk of recurrent preterm birth, (iii) that tens of thousands of women across the U.S. had, during the eight years from 2011 through 2019, unnecessarily paid for and taken Makena under a mistaken belief, now clearly shown to have been false, that the pill would reduce their risk of preterm birth, (iv) that hundreds of millions of dollars had been spent by U.S. health plans paying for a useless drug, (v) that the PROLONG Study, a study that AMAG itself had designed and carried out, conclusively

showed that Makena was useless, and (v) that the FDA had determined the study did not verify Makena's efficacy on obstetrical or neonatal outcomes.

9. Despite this knowledge and background, after the release of PROLONG Study's results and the FDA's subsequent finding that they showed Makena was useless, AMAG, astonishingly, doubled down on its false claims of Makena's efficacy for the next three-and-a-half years, from late October 2019 until April 2023. AMAG kept marketing the product as effective (when it was not), disparaged the PROLONG Study results (when those results were sound), kept the product on the market (when it knew it had no proven effectiveness), failed to counter its years of prior false marketing (while knowing those falsehoods had succeeded in increasing sales in the past), dragged out proceedings with the FDA over formal withdrawal of the product (while knowing the end was inevitable), and milked sales of Makena quarter after quarter.

10. Meanwhile, in October 2020, Covis bought AMAG for over a half-billion dollars and immediately began aiding AMAG's efforts to drag out sales of Makena and put off a final FDA withdrawal decision. Covis had a major investment to protect, and so its gameplan was to help foster sales of the useless product and cause women to unnecessarily take Makena in the hopes of handsomely profiting from its new purchase. And AMAG's and Covis's efforts were successful, causing payors and patients to needlessly spend hundreds of millions of dollars.

11. Finally, on April 6, 2023, the FDA withdrew approval of Makena.

12. This case alleges that, during the period from late October 2019 until early April 2023, AMAG and Covis unlawfully marketed, promoted, and sold in the United States a useless drug product, Makena. As a result, health plans across the country were forced to pay for a

product when its manufacturer knew there was no scientifically reliable, clinically meaningful evidence showing its effectiveness.

13. Plaintiff and members of the putative classes are third-party payors, which are entities that make payments for healthcare expenses on behalf of individuals. Third-party payors include insurance companies, union health and welfare funds, and self-insured employers, among others. As relevant here, third-party payors make payments on behalf of individuals for the costs of prescription drugs.

II. PARTIES

14. Plaintiff Cleveland Bakers and Teamsters Health & Welfare Fund is a multi-employer trust fund established to provide health and welfare benefits to collectively bargained members represented by Bakers' Union Local No. 19 and Teamsters Local No. 507. Plaintiff's principal place of business is located at 9665 Rockside Road, Valley View, Ohio 44125. As a result of Defendants' unlawful conduct, Plaintiff included Makena on its formulary during the Class Period and paid for Makena prescribed to its members between February 2022 and June 2022. Plaintiff and members of the Classes would not have included Makena on their formularies and would not have paid for, or would have paid less for, Makena if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

15. As a result of Defendants' unlawful conduct, Plaintiff and members of the Classes included Makena on their formularies and paid for millions of dollars in prescriptions for Makena, despite the fact that it was ineffective at preventing preterm birth.

16. Defendant AMAG Pharmaceuticals, Inc. is Delaware corporation with its principal place of business in Waltham, Massachusetts. AMAG is a commercial-stage biopharmaceutical company. From 2011 through April 2023, AMAG and its predecessors had

approval from the FDA to market Makena (hydroxyprogesterone caproate). AMAG has held, and continues to hold, the exclusive marketing rights to Makena since its 2014 acquisition of Lumara Health. As of November 2020, AMAG Pharmaceuticals is a wholly owned subsidiary of Covis Group S.à r.l.

17. Defendant Covis Group S.à r.l. is a Luxembourg company with its principal place of business in Zug, Switzerland. Covis Group has been the parent company of AMAG since November 2020. Covis is owned by private equity firm Apollo Global Management.

III. JURISDICTION AND VENUE

18. This action arises under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1962(c) and (d), 1964, as well as state consumer protection statutes. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 (federal question), 1332 (diversity due to a qualifying class action), and 18 U.S.C. § 1964(c) (RICO).

19. This Court also has supplemental jurisdiction over Plaintiff's state law claims pursuant to 23 U.S.C. § 1367.

20. Defendants transacts business within this district and transacts its affairs and carries out interstate trade and commerce, in substantial part, in this district and/or have an agent and/or can be found in this District. Venue is appropriate within this district under RICO, 18 U.S.C. § 1965(a), and under 28 U.S.C. §§ 1391(b) and (c).

IV. FACTUAL ALLEGATIONS

A. Hydroxyprogesterone caproate, approved and marketed as Delalutin beginning in 1956, is eventually withdrawn by the manufacturer after falling out of favor.

21. Hydroxyprogesterone caproate is a synthetic progestin, which is a steroid hormone that is part of a class of drugs comprised of synthetic forms of progesterone. Progesterone is a naturally occurring steroid hormone that has a variety of functions during

pregnancy. It thickens the endometrium, facilitates embryo implantation, and promotes gestation. Low levels of progesterone during pregnancy are correlated with miscarriages and ectopic pregnancies.

22. Synthetic progestin has existed for over half a century as a hormonal medication. Hydroxyprogesterone caproate was originally approved by the FDA in 1956. Its original labeling provided suggested dosing and administration for several indications believed to respond to progestogens but did not include prevention of preterm birth. The drug was marketed by Squibb Pharmaceuticals—today, Bristol-Myers Squibb Company ("BMS")—and sold under the brand name Delalutin.

23. No large-scale or reliable studies or evidence supported the use of Delalutin for pregnancy maintenance. But after some case studies in the 1960s suggested it may be effective in preventing preterm birth, Delalutin was increasingly prescribed for this purpose.

24. On October 10, 1973, the FDA announced that recent data suggested a possible association between prenatal hormonal treatment and congenital heart defects. The agency concluded that "[t]he potential risk of teratogenic effects is considered high enough to warrant removal of pregnancy-related indications from the labeling of progestins currently marketed for systemic use."[1] The FDA therefore required that the labeling for hydroxyprogesterone caproate be revised to exclude any indications for use during pregnancy.

25. On July 22, 1977, the FDA, based on new data indicating exposure to sex hormones during early stages of pregnancy could cause serious birth defects, announced that the labeling for all progestational drug products should be revised to include a contraindication and

[1] Medroxyprogesterone Acetate; Norethindrone; Norethindrone Acetate; Progesterone; Dydrogesterone; and Hydroxyprogesterone Caproate, 38 Fed. Reg. 27,947, 27,948 (Oct. 10, 1973), https://www.govinfo.gov/content/pkg/FR-1973-10-10/pdf/FR-1973-10-10.pdf.

warning regarding the use of such products during pregnancy. In 1978, the FDA published a final rule requiring the labeling for all progestational drug products to include a warning informing patients that their use was associated with an increased risk of birth defects.

26. Delalutin was thus prescribed sparingly between 1973 and 1999. On September 13, 1999, BMS submitted a letter to the FDA requesting the withdrawal of the Delalutin NDA because the drug had not been marketed for several years. On September 13, 2000, the FDA granted the request and officially withdrew Delalutin's approval, effective September 30, 2000.

B. The 2003 Meis Study revives interest in hydroxyprogesterone caproate as a treatment for preterm birth in at-risk women.

27. In June 2003, three years after the FDA withdrew Delalutin's approval, a study examining whether hydroxyprogesterone caproate reduced the risk of preterm labor in women whose prior pregnancies resulted in preterm delivery was published in the *New England Journal of Medicine*. The so-called Meis Study (for its lead author, Dr. Paul J. Meis) concluded that weekly injections of hydroxyprogesterone caproate substantially reduced the rate of recurrent preterm delivery among women at particularly high risk.

28. The reliability of the Meis Study was immediately questioned by some. An editorial published in the same issue of the *New England Journal of Medicine* expressed doubt as to whether the Meis Study's results could be generalized to other patient populations, noting, "The 54.9 percent incidence of preterm delivery in the placebo group is so much higher than the rates reported in other high-risk cohorts that it calls into question whether these women are representative of the U.S. population at large."[2] The article pointed out that further study of how hydroxyprogesterone caproate works was necessary to determine whether it was maladaptive for

[2] Michael F. Greene, *Progesterone and Preterm Delivery— Déjà Vu All Over Again*, 348 New Eng. J. Med. 2453 (2003), https://www.nejm.org/doi/full/10.1056/nejme030081.

certain causes of preterm labor, such as infection with virulent organisms. It also suggested longer-term follow-up with study subjects to identify any long-term consequences of treatment.

29. Nonetheless, in November 2003, based on the results of the Meis Study, the American College of Obstetricians and Gynecologists (ACOG) recommended that progesterone supplementation to prevent preterm birth be offered to pregnant women with a prior spontaneous preterm delivery.

30. Because no pharmaceutical companies were manufacturing hydroxyprogesterone caproate, local and national compounding specialty pharmacies began making inexpensive ($10–$20) injections of the drugs for use by pregnant women at risk for preterm delivery, even though the FDA had not approved use of the drug to prevent preterm labor. For nearly a decade, physicians and patients relied on compounding pharmacies to supply low-cost hydroxyprogesterone caproate on an as-needed basis.

C. AMAG predecessor Adeza files an NDA seeking accelerated approval of Gestiva for the prevention of preterm based on the Meis Study data.

31. After the Meis Study was published, AMAG predecessor Adeza Biomedical Corporation met with the FDA to discuss the possibility of using the study's data as the basis for a New Drug Application ("NDA") for hydroxyprogesterone caproate to prevent preterm birth in at-risk women. The FDA, concerned that the Meis Study had not been designed as a clinical trial to support marketing approval, recommended that Adeza obtain at least two years of follow-up safety data for the children of the mothers that had participated in the Meis Study. The FDA also advised Adeza that the agency generally requires data from at least two adequate, well-controlled clinical trials for marketing approval.

32. On April 20, 2006, Adeza submitted NDA No. 21945 to the FDA seeking approval of Gestiva, its branded version of hydroxyprogesterone caproate, for the proposed

indication of prevention of preterm birth in at-risk women. While the application included supporting data from two clinical trials and a follow-up safety study, the Meis Study remained its principal source of efficacy and safety data.

33. Adeza requested priority review of the Gestiva NDA under the FDA's accelerated approval regulations, which allow the FDA to expedite approval of drugs for serious conditions fulfilling an unmet medical need by using surrogate or intermediate clinical endpoints to evaluate efficacy. These regulations permit approval based on "a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is *reasonably likely* to predict an effect on irreversible morbidity or mortality or other clinical benefit" and "evidence to support that an endpoint is *reasonably likely* to predict clinical benefit."[3] Adeza also submitted an application to have Gestiva designated an orphan drug, which grants exclusive marketing rights for up to seven years to sponsors of applications for drug or biological products that prevent, diagnose, or treat a rare disease or condition.

D. Despite serious concerns within the agency about the safety and efficacy of hydroxyprogesterone caproate, the FDA eventually approves AMAG's NDA.

34. On June 5, 2006, the FDA granted the Gestiva NDA priority review status and set a goal of October 20, 2006 to complete its review or otherwise respond to the application.[4] During the FDA's review of the application, however, several agency reviewers raised serious concerns about and identified major deficiencies in the data Adeza submitted in support of the application. Pharmacology reviewers found there was "insufficient nonclinical data on which to

[3] 21 U.S.C. § 356 (emphasis added).

[4] *FDA Grants Adeza Priority Review for Gestiva to Prevent Preterm Births*, Drugs.com (June 5, 2006), https://www.drugs.com/nda/gestiva_060605.html.

base the safety of [hydroxyprogesterone caproate], especially in regard to long-term effects in offspring exposed in utero" and recommended that the sponsor design and conduct a multigenerational study to assess these effects.

35. The FDA's statistical reviewer, Lisa Kammerman, recommended against approval of Makena, concluding that "the level of evidence from [the Meis Study] is not sufficient to support the effectiveness of [hydroxyprogesterone caproate] and, therefore, does not support the requirements for [approval]" and that, "[w]ithout a second study, the generalizability of the study results to a larger population cannot be assessed."[5] The reviewer identified substantial deficiencies in the Meis Study, including:

- The use of a primary endpoint of preterm delivery before 37 weeks of gestation, which "is not what the FDA would have advised"[6];
- The fact that the study was not adequately powered for analysis of its secondary endpoints;
- Confidence intervals suggesting the analyses of the 32- and 35-week endpoints could have "false positive rates could be as great as 1/40"[7];
- The failure to "accommodate the range of gestational age at study entry and, therefore, the time on study drug prior to delivery"[8]; and
- The fact that the subjects from one study site accounted for 25% of all subjects and disproportionately affected the overall results.

36. Reviewers also found that "[t]he clinical trial data did not provide evidence of a clinically meaningful or statistically significant effect on neonatal morbidity or mortality."[9] They

[5] *See Statistical Review and Evaluation: Clinical Studies (21-945)* at 3–4, FDA Center for Drug Evaluation and Research (Apr. 20, 2006), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021945Orig1s000StatR.pdf.

[6] *Id.* at 4.

[7] *Id.* at 5.

[8] *Id.* at 18.

[9] *Cross Discipline Team Leader Review (NDA 21-945 Makena)* at 12, FDA Center for Drug Evaluation and Research (Feb. 3, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021945orig1s000crossr.pdf.

further noted that the data suggested "there may be more immediate safety issues, particularly involving increased early fetal loss in women treated with [hydroxyprogesterone caproate]."[10]

37. On August 29, 2006, an FDA Advisory Committee for Reproductive Health Drugs was convened to review the Gestiva NDA. The Advisory Committee unanimously agreed that further study of hydroxyprogesterone caproate was needed to evaluate the potential association of the drug with increased risk of second trimester miscarriage and stillbirth. But the committee split 13-8 in a vote on whether the additional study had to be completed before approval of Gestiva, with a slight majority finding that the Meis Study data provided sufficient evidence of efficacy and safety for accelerated approval. Even some of the committee members that voted for approval, however, expressed doubts about the drug's effectiveness and safety.

38. On October 20, 2006, the FDA issued an Approvable Letter to Adeza stating that its Gestiva NDA may meet the requirements for accelerated approval if Adeza submitted a draft protocol and evidence on the feasibility of conducting an additional multicenter, well-controlled trial to verify Gestiva's effectiveness, a draft protocol to assess the association between hydroxyprogesterone caproate and second trimester miscarriage and stillbirth, and a reproductive toxicology study. The letter further advised Adeza that post-marketing completion of these efficacy and safety studies would be required as a condition of approval.

39. On January 31, 2007, the FDA granted Adeza's request to designate Gestiva as an orphan drug.

40. On April 3, 2007, Adeza was acquired by Cytyc Corporation, which subsequently merged with Hologic, Inc. on October 22, 2007.[11]

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[10] *Id.*

[11] Press Release, Hologic, Hologic and Cytyc Complete Merger (Oct. 22, 2007), https://investors.hologic.com/press-releases/press-release-details/2007/Hologic-and-Cytyc-Complete-Merger/default.aspx.

41. In January 2008, K-V Pharmaceutical Company purchased worldwide rights to Gestiva from Hologic for $82 million, contingent upon FDA approval. K-V would be the first manufacturer to market the drug under the brand name Makena.

42. On January 23, 2009, the FDA issued a Complete Response letter to Cytyc (now Hologic) expressing concern that, because ACOG's October 2008 opinion had made progesterone treatment of patients at risk of recurrent preterm birth the *de facto* standard of care, it may not be feasible to conduct the proposed confirmatory trial—which would later be called the "PROLONG Study"—primarily in the United States. Because "adequate assurance of feasibility can only be addressed by actual initiation of the trial," the FDA required Hologic to enlist investigators at and obtain IRB approval for at least 15 U.S. and non-U.S. investigational sites and enroll at least 10% of the total sample of 1,700 subjects from U.S. and Canadian sites.[12]

43. On February 3, 2011, the FDA finally approved for Makena under the accelerated approval process, triggering the sponsor's seven-year exclusivity period. However, given the lack of evidence submitted with the NDA, the FDA's approval was explicitly conditioned on the requirement that a clinical study of the drug's efficacy be completed. Accordingly, the sponsor of the drug knew it was far from certain that Makena was actually effective at preventing preterm birth.

E. AMAG predecessor K-V Pharmaceutical launches Makena at an astonishing price of $1,500 per injection and goes after the compounded version of the drug.

44. Armed with market exclusivity for its brand version of hydroxyprogesterone caproate, K-V launched Makena in February 2011 with a breathtaking sticker price of $1,500 per injection—an increase of 7,400% over the then-prevailing price of $10–$20 per injection for the

[12] Complete Response Letter from Scott Monroe, Director, Division of Reproductive and Urologic Products, to Robb Hesley, Vice President, Business Development, Cytyc Corporation (Jan. 23, 2009), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021945Orig1s000OtherActionLtrs.pdf.

compounded version. Because Makena is designed to be administered weekly beginning between the sixteenth and the twentieth weeks of pregnancy and through the thirty-seventh week of pregnancy, a single course of treatment priced at $1,500 per injection could cost over $30,000.

45. The initial list price for Makena sparked immediate public outrage. Lawmakers decried the cost, including Senator Sherrod Brown, who sent K-V a letter asking it to "immediately reconsider" its pricing of Makena, stating he was "deeply concerned that your company appears to be taking advantage of FDA approval at the expense of women, children and federal and state budgets.[13] The nonprofit organization The March of Dimes announced plans to terminate its partnership with K-V because "[t]he company's handling of the launch of Makena, and the initial list price, were highly unsatisfactory and unacceptable to the March of Dimes and the families we represent."[14]

46. K-V initially defended its pricing of Makena, but eventually cowed to the intense public backlash. On April 1, 2011, K-V announced that it would reduce the list price of Makena by 55% to $690 per shot—still more than 40 times what compounding pharmacies had been charging for the nearly 60-year-old generic medicine—and announced that it would pursue rebates and financial assistance programs to help defray the cost of the drug.

47. K-V also launched an aggressive campaign against the compounded version of hydroxyprogesterone caproate to pressure doctors to prescribe and third-party payors to cover branded Makena. In February 2011, it began sending "cease and desist" letters to compounding pharmacies, informing them that K-V had an exclusive right to sell hydroxyprogesterone

[13] Maia Szalavitz, *KV Backlash: Senator Condemns Pregnancy Drug Price Hike*, Time (Mar. 11, 2011), https://healthland.time.com/2011/03/11/kv-backlash-senator-condemns-pregnancy-drug-price-hike/.

[14] Peter Loftus, *K-V Pharma Slashes Price of Drug Amid Outcry*, The Wall Street Journal (Apr. 1, 2011), https://www.wsj.com/articles/SB10001424052748703806304576236980798831262.

caproate and demanding that they immediately stop selling compounded versions of the drug to consumers.

48. On March 30, 2011, the FDA responded by issuing a public statement flatly rejecting K-V's claims, stating: "FDA understands that the manufacturer of Makena (hydroxyprogesterone caproate), KV Pharmaceutical, has sent letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compound versions of Makena. *This is not correct*." The FDA clarified that, "[i]n order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products."[15]

49. On July 5, 2012, K-V sued the FDA in the U.S. District Court for the District of Columbia alleging that the agency's failure to take enforcement action against pharmacies that compound hydroxyprogesterone caproate violated the APA and FDCA and caused K-V irreparable economic harm by allowing unlawful competition with Makena. The court dismissed the case for failure to state a claim.

50. K-V nonetheless continued to make false statements to patients, physicians, and payors disparaging the potency, purity, and safety of compounded hydroxyprogesterone caproate. Indeed, "[t]here have been no published data to suggest the efficacy of the compounded 17P is different from that of the FDA-approved drug," and multiple studies have concluded that

[15] *FDA Will Not Take Action Against Pharmacies Compounding Cheaper Makena*, FDA News (Mar. 31, 2011), https://www.fdanews.com/articles/135538-fda-will-not-take-action-against-pharmacies-compounding-cheaper-makena.

"compounded 17P did not raise safety concerns when compared with the FDA-approved product."[16]

51. K-V struggled to meet its sales goals for Makena, and, on August 11, 2012, filed for Chapter 11 bankruptcy. It emerged from bankruptcy and changed its name to Lumara Health in May 2014.

F. AMAG acquires Lumara Health and launches an aggressive campaign to maximize profits from Makena.

52. On September 29, 2014, Defendant AMAG announced that it had entered into an agreement to acquire Lumara Health and its drug portfolio for $675 million, with an additional $350 million contingent on sales milestones. The acquisition was completed on November 12, 2014.

53. To take full advantage of the remaining marketing exclusivity period for Makena, AMAG launched an aggressive marketing campaign aimed at convincing prescribers, patients, and third-party payors that Makena was an effective drug for preventing preterm birth. At all times, Defendants knew and understood that third-party payors were critically important to its bottom line, because they would be responsible for paying most of the costs related to Makena.

54. In a 2015 presentation to investors, AMAG executives described a "$1B Makena Market Opportunity" and projected $1 billion in annual sales if the company reached its goal of 140,000 patients receiving 16 injections during their pregnancies.[17]

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[16] Arnold W. Cohen & Samuel Parry, *Compounded 17-Hydroxyprogesterone Caproate Is an Inexpensive and Safe Alternative to the FDA-Approved Product*, 210 Am. J. Obstetrics & Gynecology 12, 13 (2014), https://www.ajog.org/article/S0002-9378(13)02018-8/fulltext.

[17] Melody Petersen, *A Drug for Pregnant Women Doesn't Work, According to the FDA. A Company Is Selling it Anyway*, L.A. Times (Feb. 17, 2022), https://www.latimes.com/business/story/2022-02-17/makena-covis-premature-birth-pregnant-womens-health/.

55. The presentation also indicated that AMAG's "growth strategy" was focused on three key groups: prescribing physicians, professional medical societies, and nonprofit patient groups that advocate for pregnant women.

1. Despite paltry clinical evidence, Defendants tout Makena's efficacy to patients, physicians, and payors.

56. Defendants' marketing messages about Makena did not mince words. Instead, they focused on convincing patients, doctors, and payors of the effectiveness that Defendants knew was dubious. For instance, Defendants distributed brochures asserting that Makena "helps you get closer to term," "lower[s] the risk of having another preterm," and "helps give baby more time to develop."[18] They emphasized that, for pregnant women at risk of preterm delivery, "every week counts."[19]

[18] *Makena Auto-Injector Patient Education Brochure*, Makena Care Connection, https://makenahcp.com/wp-content/themes/MakenaHCP/file/Makena_Auto-Injector_Patient_Education_Brochure_-_English.pdf (last accessed July 20, 2023).

[19] *Id.*

57. Similarly, on their website, Defendants asserted that "Makena helps [women] get closer to term"[20] and "lower[s] the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37

[20] *Reducing Risk with Makena Auto-Injector*, AMAG Pharmaceuticals, Inc., https://makena.com/reducing-preterm-birth-risk-with-makena/ (last accessed July 21, 2023).

weeks) in the past."[21] Defendants also repeatedly claimed "Makena gives moms an extra layer of support" and cited testimonials from patients who were purportedly receiving "peace of mind" from taking Makena.[22]

58. Makena's website for healthcare providers also stated that the drug is "For Your Patients at Risk for Another Singleton Spontaneous Preterm Birth (<37 Weeks)."[23] It further stated that "Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered <37 weeks of gestation."[24]

59. Each of these messages were false and misleading because AMAG knew that Makena could not give babies more time to develop, bring expectant mothers closer to term, or reduce the risk of future preterm deliveries. Every single marketing message Defendants put forth omitted the fact that Makena was no better than a placebo at preventing preterm birth. Following the release of the results of the PROLONG Study, Defendants further had a duty to

[21] *Id.*

[22] *Id.*

[23] *Makena*, AMAG Pharmaceuticals, Inc., https://makenahcp.com/ (last visited May 26, 2023).

[24] *Id.*

correct these misleading and false statements. Not only did Defendants fail to do so, they continued to maintain that Makena was effective at preventing preterm birth.

2. Defendants target third-party payors.

60. Upon information and belief, AMAG's false and misleading statements and omissions about Makena's efficacy were intended to cause third-party payors, including Plaintiff and members of the Classes, to include Makena on their formularies and pay for expensive and excessive prescriptions of Makena, which AMAG was selling at inflated prices.

61. Critically, coverage of prescription drugs under the plans that Plaintiff and Class members offer are based on a formulary, which is a list of the drugs that are approved for coverage. Plaintiff and similarly situated Class members work with Pharmaceutical Benefits Managers ("PBM") who prepare the formulary.

62. To be listed on the formulary, a drug must be assessed for clinical safety, efficacy, and cost effectiveness by the PBM. Where a PBM determines that a drug has an advantage over competing drugs, that drug is given preferred status on its formulary.

63. Preference on a formulary impacts the amount that a plan participant must contribute as a co-payment when purchasing a drug—the greater the preference shown to a drug on the formulary, the lower the co-payment required from the plan participant. Thus, preference on a formulary makes it more likely that the drug will be purchased by a plan beneficiary over a cheaper or more cost-effective alternative. This, in turn, means that the higher a drug's preference on a formulary, the greater the likelihood that a doctor will prescribe that drug. This system exists across the health insurance industry and is well known to pharmaceutical manufacturers and AMAG.

64. Because placement on a third-party payors' formulary determines whether a third-party payor will pay for a drug, to promote the sale of Makena, it was necessary for AMAG and its predecessors to ensure favorable treatment on third-party payors' formularies.

65. Accordingly, AMAG's false and misleading representations and omissions as to Makena's efficacy caused third-party payors, including Plaintiff and Class members, to place Makena on their formularies and/or to give Makena more favorable treatment on their formularies than the less expensive compounded drug. As part of these deliberate efforts to have third-party payors include and/or give Makena favorable treatment on their formularies, and ultimately to pay for Makena, AMAG and its predecessors engaged directly with third-party payors like Plaintiff and Class members. Specifically, AMAG entered into rebate agreements with numerous third-party payors, and acted as an intermediary between patients and their third-party payors in an effort to ensure that third-party payors skeptical of Makena's high price tag would nevertheless pay for the drug.

3. Defendants created an enterprise of medical marketing firms, physicians, hospitals, and professional associations to deceptively promote Makena.

66. In order to carry out its aggressive marketing scheme, Defendants created the Makena Promotion enterprise, comprised of, *inter alia*, Defendants, medical marketing firms, numerous physicians, professional associations, and astroturf groups which hide their sponsorship in order to falsely present themselves as grassroots organizations. These participants acted together to falsely and deceptively promote Makena, including to third-party payors, prospective patients, and prescribers of the drug.

a. Makena Care Connection Enterprises

67. Specifically, AMAG, the CDM Group, AllCare Plus Pharmacy, LLC, and PPD Medical Communications to conduct a direct marketing campaign known as "Makena Care

Connection," which directly engaged current and prospective patients to encourage them to seek out Makena.[25] Makena Care Connection also targeted healthcare providers and third-party payors to increase the number of prescriptions made for Makena and ensure coverage—and thus payment—by third-party payors.

68. To meet its goal of increasing the volume of sales of Makena at exorbitant prices, AMAG needed to ensure that doctors prescribed hydroxyprogesterone caproate to treat possible preterm birth. If prescribed, prescriptions for hydroxyprogesterone caproate resulted in the dispensing of the name brand product Makena and not the much cheaper compounded version of the drug. Defendant and its predecessors recognized that, given the significant price difference between Makena and the already existing compounded version, third-party payors would reasonably be suspect of paying substantially more for an equivalent product and this would potentially be a significant obstacle in their push to drive sales of Makena.

69. To that end, one of the primary purposes of Makena Care Connection was coaching patients and healthcare providers on how to induce third-party payors to pay for Makena. Indeed, as acknowledged in filings with the Securities and Exchange Commission, the "[a]dministrative and treatment support" provided by Makena Care Connection "includes insurance benefit investigation."[26]

70. Through Makena Care Connection, healthcare providers were provided with talking points to use when they "encounter a denial of coverage for Makena, or prior authorization before a plan will cover Makena."[27] In such situations, the company provided

[25] K-V Pharmaceutical Co., Annual Report (Form 10-K) (June 14, 2012).

[26] *Id.*

[27] Information to Support Healthcare Provider's Medical Judgment to Prescribe FDA-Approved Makena (hydroxyprogesterone caproate injection) for Purposes of Health Insurance Coverage, Ther-Rx Corp. (Aug. 2013),

recommended arguments prescribers could use to overcome objections and convince third-party payors to cover the company's more expensive drug. A sampling of these statements included:

- "Only Makena has been studied in a controlled clinical trial (Level I evidence) to reduce the risk of preterm birth in its indicated population."
- "I want my patient to have an FDA-approved drug."
- "FDA has stated on multiple occasions that FDA-approved medications, such as Makena, provide a greater assurance of safety and effectiveness than compounded drug."
- "FDA's June 2012 statement is explicit that the FDA-approved drug should be prescribed and used, unless a compounded product provides a 'significant difference' for my patient. My patient's clinical needs are best served by the medication that has an affirmative showing of safety and efficacy, and only Makena has demonstrated that [for this indication]."[28]

71. AMAG also went further than merely providing prescribers with talking points. Through Makena Care Connection, the members of the Makena Promotion Enterprise interposed themselves between doctors and pharmacies for the sole purpose of facilitating coverage by third-party payors. A Summer 2022 "Billing Guide" provided to healthcare providers states that "[a]s a specialty injectable, Makena can be covered by insurance plans as a pharmacy or medical benefit. Your patient's insurance plan will determine how Makena is covered."[29] It further directed prescribers to "submit the Makena Prescription Form to Makena Care Connection via fax."[30] The prescription form was created by AMAG, and states that it should be completed and sent to Makena Care Connection with copies of the patient's insurance card. From there, Makena

Zamfirova v. AMAG Pharms., Inc., No. 2:20-cv-0152, ECF 66-1 (D.N.J. June 24, 2021). Ther-Rx Corporation was the wholly owned subsidiary of K-V that marketed the company's name brand drugs. K-V Pharmaceutical Co., Annual Report (Form 10-K) n.22 (June 14, 2012).

[28] *Id.*

[29] *Makena® (Hydroxprogesterone Caproate Injection) Billing Guide: Summer 2022*, Makena Care Connection (2022), https://makenahcp.com/wp-content/uploads/2022/08/Makena-Auto-Injector-Billing-Guide.pdf.

[30] *Id.*

Care Connection "investigates the patients insurance benefits, and upon approval, sends the Makena prescription to the payer-preferred dispensing pharmacy for processing."[31]

72. Makena Care Connection also facilitated communications directly with patients, which were similarly designed to induce third-party payors into paying for Makena. The company directed patients to take the "following steps" to "ensure you have access to all the support Makena Care Connection has to offer":

- "REQUEST branded Makena so that Makena Care Connection may continue to provide you support."
- "VERIFY with your pharmacist that Makena is being dispensed *before paying your out-of-pocket expense* and/or approving the shipment."
- "TALK with our healthcare provider or Makena Care Connection if the product you received does not state Makena on the packaging."[32]

73. AMAG similarly sought to directly target third-party payors through Makena Care Connection by encouraging patients to use Makena Care Connection as a "layer" between themselves and third-party payors. Its Patient Education Brochure states that "[w]hen you start Makena® (hydroxyprogesterone caproate injection) Auto-Injector, you get more than the medicine. You get personalized resources that are specifically designed to help you throughout your experience with Makena. Think of us as an extra layer of support."[33]

74. This "extra layer" was clearly intended to create a channel through which AMAG could directly pressure third-party payors to pay for Makena. According to the brochure, Makena Care Connection "[h]elps you get your prescription approved in a timely manner."[34] It further

[31] *Makena® Prescription Form*, Amag Pharmaceuticals, Inc. (2022), https://makenahcp.com/wp-content/uploads/2022/05/Makena-Auto-Injector-Prescription-Form-2022-Digital.pdf.

[32] *Makena Care Connection Welcome Letter*, Makena Care Connection (2018).

[33] *Id.*

[34] *Id.*

states that "[y]ou're unique and so are your insurance benefits. Because getting your medicine in a timely manner is important, we're here to lend a hand. *We have a dedicated team who understands the coverage policies for Makena. Our experts can handle the details between your healthcare professional, insurance company, and pharmacy* so you receive your Makena when you need it."[35]

75. While not reducing costs for third-party payors that would pay the bulk of Makena's expense, the marketing materials for Makena touted the financial subsidies provided by Makena Care Connection to patients. For instance, Makena's Patient Education Brochure stated that Makena Care Connection "[h]elps ensure affordable access to Makena," and for "[c]ommercially insured moms" it "[h]elps lower out-of-pocket costs associated with copays, coinsurance, and deductibles" that is "[b]ased on a sliding scale from $0–$35/injection."[36] Thus, patients were given a financial incentive to demand name-brand Makena from doctors and coverage for the drug from their third-party payors.

b. Physicians and Hospitals

76. The Makena Promotion Enterprise also facilitated its fraudulent scheme to misrepresent the efficacy of Makena at preventing preterm birth by paying thousands of dollars to maintain a network of 5,800 doctors and 16 hospitals to influence prescribing decisions and increase the number of patients being treated with Makena.

77. In 2015, AMAG told its investors that it had created a "publications committee" comprised of key opinion leaders. AMAG paid these key opinion leaders to persuade their peers

[35] *Id.*

[36] *Id.*

to prescribe Makena by publishing journal articles and giving speeches supporting the drug's safety and efficacy and promoting distrust for the compounded version.

78. AMAG engaged in years-long payments to doctors to promote their false and misleading claims and omissions about Makena's effectiveness. For example:

- AMAG has paid Dr. Baha Sibai $111,167.80 since 2016. Dr. Sibai has authored numerous journal articles promoting Makena as safe and clinically effective. Not only did Dr. Sibai publish supportive pieces in medical journals, he was also presented by AMAG as an "independent maternal fetal medicine physician"[37] at the meeting of the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee considering the results of the PROLONG Study. In the two months following his testimony, AMAG paid Dr. Sibai $33,000.

- AMAG has paid Dr. George R. Saade $49,149.13 since 2016. Dr. Saade has co-authored at least two journal articles promoting Makena as safe and clinically effective at preventing preterm birth.

- AMAG has paid Dr. David L. Gandell $164,007.65 since 2016. Dr. Gandell has served as the lead author on at least one journal article promoting Makena as safe and clinically effective at preventing preterm birth.

79. Notably, AMAG paid doctors to do more than simply promote Makena to patients. For example, AMAG also engaged physicians to promote Makena on podcasts.

c. Professional Associations

80. Beyond individual doctors, AMAG has also targeted the professional associations that set the standards of practice for obstetrics.

i. ACOG Enterprise

81. The American College of Obstetricians and Gynecologists (ACOG) is "the premier professional membership organization for obstetrician-gynecologists."[38] Boasting over

[37] Transcript for the October 29, 2019 Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee, Ctr. Drug Evaluation & Rsch., at 221:6-7, https://www.fda.gov/media/136108/download.

[38] *About*, Am. Col. Obstetricians & Gynecologists, https://www.acog.org/about (last visited Oct. 27, 2023).

60,000 members, among its various activities ACOG "produces practice guidelines for healthcare professionals."[39]

82. During its time marketing Makena, AMAG has been a top contributor to ACOG. In 2018, AMAG contributed $200,000 to the College's annual conference, and contributed another $50,000 the following year. AMAG's contributions were large enough to have it named as a sponsor of the College's "President's Cabinet."[40]

83. In August 2021, after the FDA's advisory panel had recommended that the agency withdraw Makena's approval, ACOG issued an updated practice bulletin recommending that patients still be prescribed Makena. The bulletin mentioned neither the FDA committee's recommendation, nor AMAG's status as a key contributor to the College.

i. SMFM Enterprise

84. In addition, the Society for Maternal-Fetal Medicine ("SMFM") is a "national voice for clinicians and researchers with expertise in high-risk pregnancy."[41] SMFM's 5,000+ members include "obstetricians with additional years of formal training and a board certification in maternal-fetal medicine, making them highly qualified experts and leaders in the care of complicated pregnancies."[42] SMFM "publishes clinical guidance on a range of high-risk pregnancy topics."[43]

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[39] *Id.*

[40] Melody Petersen, *A Drug for Pregnant Women Doesn't Work, According to the FDA. A Company is Selling it Anyway*, L.A. Times (Feb. 17, 2022), https://www.latimes.com/business/story/2022-02-17/makena-covis-premature-birth-pregnant-womens-health.

[41] *What Is the Society for Maternal-Fetal Medicine?*, Soc'y Maternal-Fetal Med., https://www.smfm.org/what-is-the-society (last visited Oct. 27, 2023).

[42] *Id.*

[43] *Id.*

85. AMAG became "a top financial supporter of the society and its events." AMAG was identified in the program for SMFM's 2019 annual meeting as "the top corporate funder of the group's foundation, giving at least $100,000," and a L.A. Times investigation found "similar contributions going back to 2015."[44]

86. SMFM has "continued to support the use of Makena despite the lack of scientific data that it works."[45]

87. AMAG and its successor Covis have "repeatedly cited the two groups' recommendations for prescribing Makena in documents it submitted to the FDA demanding the drug stay on the market."[46]

d. National Consumer League Enterprise

88. Through the National Consumer League, Covis funded the Preterm Birth Prevention Alliance.

89. This group was launched on April 20, 2021, in the midst of an FDA process to withdraw Makena from the market and received funding from Covis.

90. Despite growing evidence to the contrary, the group asserted that Makena was effective at preventing preterm birth and lobbied to keep Makena on the market without disclosing that Covis had created the group.

91. The organization echoed its' funder Covis' arguments, claiming that the results of the PROLONG study were not conclusive because the study was not "inclusive of women in the

[44] Melody Petersen, *A Drug for Pregnant Women Doesn't Work, According to the FDA. A Company is Selling it Anyway*, L.A. Times (Feb. 17, 2022), https://www.latimes.com/business/story/2022-02-17/makena-covis-premature-birth-pregnant-womens-health.

[45] *Id.*

[46] *Id.*

U.S. most vulnerable to preterm birth."[47] Like Covis, the group maintained that the Meis study was more representative of the population in the United States at risk for pre-term birth.

92. These knowingly false arguments were contradicted by the studies themselves. The Meis study enrolled a total of 463 participants, while the PROLONG study included 391 participants in the United States alone. Not only did the PROLONG study conclude that Makena was ineffective, it also included sub-group analyses that showed that the drug provided no statistically significant benefit over a placebo for both women enrolled in the United States and Black women overall.

G. Defendants' ruthless promotional efforts were spectacularly successful.

93. By any measure, AMAG's false and misleading omissions and marketing efforts were spectacularly successful. Indeed by 2012—just one year after Makena entered the U.S. market, AMAG's predecessor expressly recognized that its efforts were working: "We are actively engaging the physician and payer communities and the success of our focused outreach is evidenced by Makena®'s improving performance metrics."[48] The company further announced that it had "signed contracts with six major commercial insurers that [they] estimate[d] [would] cover more than 60 million lives."[49]

94. In 2015, Makena generated $251 million in revenue for AMAG in the first full year after its acquisition of Lumara Health. By 2016, AMAG's annual revenue was $532.1

[47] *Leading Patient Advocates Launch Preterm Birth Prevention Alliance to Protect Critical Access to the Sole FDA-Approved Class of Therapies to Reduce Recurrent Preterm Birth*, Preterm Birth Prevention Alliance, https://nclnet.org/pbp/ (last accessed Oct. 27, 2023).

[48] K-V Pharmaceutical Co., Annual Report (Form 10-K) (June 14, 2012).

[49] *Id.*

million, "primarily driven by record sales for . . . Makena."[50] That year, Makena accounted for 63% of AMAG's total net revenues. Sales of Makena continued to drive AMAG's financial health—in 2018, AMAG's annual revenue from Makena was $322.3 million, of its $474 million total revenue. In 2019, Makena accounted for $120 million of AMAG's $326 million total revenue.

95. AMAG sought every advantage to generate profits from a drug it hadn't developed, including by gaming intellectual property protections to extend its market exclusivity. Faced with the expiration of the market exclusivity provided by its orphan drug designation, AMAG developed an auto-injector device intended to launch "prior to the loss of current exclusivity in February 2018."[51]

96. The auto-injector launched in 2018 following FDA approval, and quickly served its intended purpose. Unlike intramuscular Makena, the Makena auto-injector faced no generic competition. And, despite boasting a much higher price tag than generic intramuscular hydroxyprogesterone caproate, the Makena auto-injector captured 63% of the market by the fourth quarter of 2019.

H. Defendants knew there was no support for their claims about Makena's effectiveness and safety, and its marketing materials omitted material information.

1. AMAG knew the Meis Study was flawed and did not support its efficacy claims.

97. AMAG knew that the NDA for Makena relied entirely on the flawed 2003 Meis Study to demonstrate the drug's effectiveness.

[50] *AMAG Reports Fourth Quarter and Full Year 2016 Financial Results*, GlobeNewswire (Feb. 14, 2017), https://www.globenewswire.com/news-release/2017/02/14/916861/0/en/AMAG-Reports-Fourth-Quarter-and-Full-Year-2016-Financial-Results.html.

[51] AMAG Pharmaceuticals, Inc., Annual Report (Form 10-K) (Feb. 24, 2016).

98. And AMAG was aware of the flaws in the Meis Study at the time it began marketing Makena. Indeed, the FDA's own *Statistical Review and Evaluation* of Makena's New Drug Application noted that "[f]rom a statistical perspective, the information and data submitted by the Applicant do not provide convincing evidence regarding the effectiveness of 17 α-hydroxyprogesterone, caproate injection (17P) for the prevention of preterm deliveries among women with a history of at least one spontaneous preterm delivery."[52]

99. Given the dearth of support for Makena's efficacy—including from the Meis Study—Makena's accelerated approval was conditioned on the results of a post-marketing study to confirm the drug's clinical effect.

100. Despite the known flaws with the Meis Study and the need to conduct an additional trial to determine whether Makena was effective at preventing preterm birth, AMAG made fraudulent and misleading misrepresentations and omissions about Makena's efficacy to Plaintiff and other Class members.

2. AMAG had access to patient narratives and adverse event information show Makena's lack of efficacy.

101. On information and belief, AMAG was provided with narratives from patients who took the drug, confirming it did not prevent preterm birth. Through Makena Care Connection, AMAG heard from numerous Makena-prescribed mothers who informed the company that, despite paying thousands of dollars for the drug, they nevertheless delivered prior to 37 weeks.

102. Confirming these reports of inefficacy that were provided directly to AMAG, data from the FDA Adverse Events Reporting System (FAERS) also indicated that preterm birth

[52] AMAG Pharmaceuticals, Inc., Annual Report (Form 10-K) (Mar. 6, 2020).

remained a concern among patients prescribed Makena. In fact, Preterm birth was the top adverse reaction in the database for Makena every year from 2011 to 2018. In total, there were 2,917 reports of preterm birth adverse events for patients prescribed Makena.

3. Defendants had access to non-public information about the failed PROLONG Study before it was published.

103. While the public did not know of Makena's lack of clinical effectiveness until after the FDA removed Makena from the market in April 2023, based on its direct involvement with the PROLONG Study, AMAG has known, or had reason to know, since the time it began marketing Makena that the drug is ineffective at preventing preterm birth.

104. The first participant was enrolled in the PROLONG Study in 2009, and the final participant provided their final data in 2018. Over the course of those nine years, 1,587 participants were randomized and completed the study.

105. Shortly after acquiring KV, on December 11, 2014, AMAG was named a Collaborator on the PROLONG Study. A Collaborator is an organization that "provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting."[53] As a result of its role as a Collaborator, AMAG had inside knowledge about the study results that it concealed from Plaintiff and members of the Classes.

106. AMAG continued to gain additional control of the study and acquire additional knowledge about the data and results. On April 6, 2016, the Study Protocol for the PROLONG Study was amended and listed "AMAG Pharma USA, Inc." as the study's Sponsor. A Sponsor is "[t]he organization or person who initiates the study and who has authority and control over the

[53] *Glossary of Common Site Terms*, ClinicalTrials.gov, https://clinicaltrials.gov/ct2/about-studies/glossary (last visited Oct. 27, 2023).

study."[54] As a result of its role as Sponsor and its corresponding federal reporting requirements, AMAG knew about the study results, but concealed this information from Plaintiff and members of the Classes.

107. Under federal regulations, a study's Sponsor is specifically required to monitor the safety and efficacy of the studied drug and provide periodic reporting to the FDA. To that end, 21 C.F.R. § 312.56(c) provides that "[t]he sponsor *shall review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator.* The sponsors shall make such reports to FDA regarding information relevant to the safety of the drug as are required under § 312.32. The sponsor shall make annual reports on the progress of the investigation in accordance with § 312.33."

108. Annual reporting under § 312.33 requires the sponsor to provide "a brief description of *any available study results*."[55] The Sponsor must also provide "[i]nformation obtained during the previous year's clinical and nonclinical investigations, including . . . [a] brief description of what, if anything, was obtained that is *pertinent to an understanding of the drug's actions, including*, for example, information about dose response, *information from controlled trials*, and information about bioavailability."[56]

109. In addition to the interim reporting requirements imposed by law, AMAG also had knowledge about the results of the study through its employees. The authors of the PROLONG Study included then-current or former AMAG employees Jennifer Gudeman, Robert

[54] *See* Study Protocol IND Number: 68,108 A Phase 3B, Multi-center, Randomized, Double-Blind Study of Hydroxyprogesterone Caproate Injection, 250 MG/ML, Versus Vehicle for the Prevention of Preterm Birth in Women with a Previous Singleton Spontaneous Preterm Delivery, ClinicalTrials.gov (Apr. 6, 2016), https://clinicaltrials.gov/ProvidedDocs/29/NCT01004029/Prot_000.pdf.note 9.

[55] 21 C.F.R. § 312.33(a)(3).

[56] 21 C.F.R. § 312.33(b)(5).

Birch, Michael J. Jozwiakowski, Monique Duncan, Laura Williams, and Julie Krop. AMAG also inherited the knowledge of its predecessors Lumara Health and KV Pharmaceuticals—previous sponsors of the PROLONG Study—through their acquisition of the company, operation of Lumara as a division, and the retention of key personnel.

110. Given AMAG's role as Collaborator and Sponsor of the PROLONG Study, and the fact that its own employees were directly involved in the study, upon information and belief, AMAG had access to data from the PROLONG study, which demonstrated Makena's ineffectiveness, for years before the results were announced and the drug was withdrawn.

I. The 2019 PROLONG study confirms what Defendants already knew—that Makena was not effective at preventing preterm birth.

111. On March 8, 2019, AMAG announced what is characterized as the "topline results" of the PROLONG Study. These "topline results" showed that the trial "did not demonstrate a statistically significant difference between the treatment and placebo arms for the co-primary endpoints: the incidence of preterm delivery at less than 35 weeks . . . and the percentage of patients who met criteria for the pre-specified neonatal morbidity and mortality composite index."[57] The topline results showed that 11.0% of participants treated with Makena experienced preterm delivery at less than 35 weeks, compared to 11.5% of participants receiving a placebo.

112. At the time of AMAG's top line results announcement, the full PROLONG Study had not yet been published, and complete details were unavailable to the public, including Plaintiff and Class members. Moreover, when announcing the topline results of the PROLONG

[57] *AMAG Pharmaceuticals Announces Topline Results from the PROLONG Trial Evaluating Makena® (Hydroxyprogesterone Caproate Injection)*, AMAG Pharmaceuticals, Inc. (Mar. 8, 2019), https://www.amagpharma.com/news/amag-pharmaceuticals-announces-topline-results-from-the-prolong-trial-evaluating-makena-hydroxyprogesterone-caproate-injection/.

Study, AMAG sought to cast doubt on its findings, despite having a role in the study's design and implementation. For example, the company attacked the study for enrolling participants "outside of the U.S., predominantly from Eastern European countries."[58]

113. Thereafter, the "American College of Obstetricians and Gynecologists, the Society for Maternal-Fetal Medicine and March of Dimes" stated "they stand by their current recommendations of synthetic hormone injections and will evaluate information as it comes to light."[59]

114. On October 25, 2019, the full PROLONG Study was published in the American Journal of Perinatology. When announcing the publication of the study, AMAG sought to downplay its significance by noting its "contrast to the original Meis trial results published in the New England Journal of Medicine," even though AMAG knew that both studies were found by the FDA's advisory committee to not support the drug's effectiveness.[60]

115. A fundamental principle that guides the evaluation of a pharmaceutical product is whether the drug's health benefits outweigh its risks. As the results of the Meis Study and PROLONG Study showed, Makena is not effective at preventing preterm birth. That should have precluded AMAG's false and misleading misstatements and omissions regarding the drug's efficacy.

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[58] *AMAG Pregnancy Drug's Future in Doubt After Key Study Miss*, BioPharmaDive (Mar. 8, 2019), https://www.biopharmadive.com/news/amag-pregnancy-drugs-future-in-doubt-after-key-study-miss/550101/.

[59] *Id.*

[60] *AMAG Pharmaceuticals Announces the Publication of the PROLONG Trial Evaluating 17-OHPC in the American Journal of Perinatology*, AMAG Pharmaceuticals, Inc. (Oct. 25, 2019), https://www.amagpharma.com/news/amag-pharmaceuticals-announces-the-publication-of-the-prolong-trial-evaluating-17-ohpc-in-the-american-journal-of-perinatology/.

J. An October 2019 FDA advisory committee unanimously agrees that the PROLONG Study failed to verify Makena's clinical benefit and finds no substantial evidence of its efficacy in reducing preterm birth, but AMAG continues to publicly downplay the trial results.

116. On October 29, 2019, in response to the PROLONG Study's failure to verify Makena's efficacy on obstetrical or neonatal outcomes, the FDA convened a meeting of its Bone, Reproductive and Urologic Drugs Advisory Committee ("BRUDAC"). The agency asked the committee to consider "whether there remains substantial evidence of effectiveness of Makena on preterm birth, the unconfirmed clinical benefit of Makena on neonatal outcomes, and implications for Makena's marketing status."[61]

117. In a briefing document for the BRUDAC meeting, the FDA directly countered AMAG's claims that differences in the study populations of the Meis Study and the PROLONG Study may have contributed to their disparate outcomes, reporting that exploratory subgroup analyses and comparisons of the study populations found no relevant differences in the treatment effect when analyzed by U.S./non-U.S. region. The FDA also reported that, although the Meis Study had a greater proportion of subjects with certain risk factors for preterm birth, including Black women, there was no evidence this had impacted the treatment effect, nor was there "consistent, convincing evidence of a treatment benefit within a specific subpopulation across the two trials."[62]

118. After considering the evidence, the BRUDAC voted unanimously (16-0) that the findings of the confirmatory did not verify the clinical benefit of Makena on neonatal outcomes and voted 13-3 that there was not substantial evidence to support the effectiveness of Makena in

[61] *FDA Briefing Document for NDA 021945, Hydroxyprogesterone Caproate Injection (Trade Name Makena)* at 9–10, FDA (Oct. 29, 2019), https://www.fda.gov/media/132003/download.

[62] *Id.* at 10–11.

reducing the risk of recurrent preterm birth. On the question of whether (a) the FDA should pursue the withdrawal of marketing approval for Makena, (b) Makena should remain on the market while a new confirmatory trial was conducted, or (c) Makena should remain on the market without a new confirmatory trial, nine members voted for option (a), seven voted for option (b), and zero voted for option (c).

119. The same day, ACOG and SMFM issued statements reaffirming their support for the use of Makena by women at risk for recurrent preterm birth.

120. In AMAG's third quarter earnings call, held three days after the panel review, AMAG executives criticized the advisory committee as "overpopulated with statisticians" who "had a harder time really understanding the nuances of maternal health care." They continued to assert the FDA-debunked claim that the PROLONG Study "was not representative of the U.S. population," while the Meis Study, in contrast, "studied a very different patient population of high-risk women and . . . definitely demonstrated efficacy." Executives also pointed to ACOG's and SMFM's reiteration of support for Makena as evidence that clinical community remained supportive of Makena's efficacy and safety and wanted it to remain on the market. They reminded investors that the advisory committee's vote "is not binding," that Makena "remains available," and that the company was "focused on . . . ensur[ing]" that "Makena remains on the market."[63]

[63] *AMAG Pharmaceuticals, Inc. (AMAG) CEO Bill Heiden on Q3 2019 Results – Earnings Call Transcript*, Seeking Alpha (Nov. 1, 2019), https://seekingalpha.com/article/4301526-amag-pharmaceuticals-inc-amag-ceo-bill-heiden-on-q3-2019-results-earnings-call-transcript.

K. Apollo-backed Covis Pharma acquires AMAG and resists the FDA's efforts to withdraw Makena's approval while engaging in a ruthless marketing campaign to maximize sales.

121. On February 7, 2020, private equity firm Apollo Global Management, which touts its ability to "generate excess risk-adjusted returns,"[64] outbid other private equity firms to buy drugmaker Covis Pharma from rival private equity firm Cerberus Capital Management for more than $700 million.

122. Eight months later, on October 1, 2020, AMAG announced that Covis Pharma, whose board of directors included Apollo Partner Sam Feinstein, Apollo Principal Michael Saffer, and Apollo Associate Robert Sorrel, had agreed to acquire AMAG for $647 million.

123. Under the terms of the agreement, AMAG would operate "as part of the Covis Pharma Group," which was "led by Covis CEO Michael Porter."[65] The agreement also sought to ensure the continuation of AMAG's marketing of Makena, by offering key AMAG employees involved with Makena retention bonuses to continue working for the company following the merger.

124. Given the fact that sales of Makena made up a substantial portion of AMAG's profits, upon information and belief, there would have been no reason for Covis's acquisition of AMAG absent a concerted plan to extend sales of Makena as long as possible despite the fact that PROLONG had conclusively shown that Makena is ineffective at preventing preterm birth.

125. On October 5, 2020, the FDA proposed withdrawing accelerated approval for Makena based on the PROLONG Study's failure to verify clinical benefit of the drug and the lack of evidence showing Makena was effective for its approved use. The notice advised Covis

[64] *Apollo Global Management*, Apollo (2023), https://www.apollo.com/.

[65] AMAG Pharmaceuticals, Inc., Solicitation/Recommendation Statement n.139 (Schedule 14D-9) (Oct. 15, 2020).

that it could submit a written request for a hearing on the proposal within 15 days and, if a hearing was sought, had 30 days to submit data, information, and analyses demonstrating a genuine and substantial issue of material fact that requires a hearing.

126. Covis submitted a timely hearing request on October 14, 2020, and sought an additional thirty days in which to respond.

127. Defendants knew requesting a hearing would prolong the withdrawal process, buying them additional months or years to reap additional profits from Makena sales. In AMAG's Q3 2019 earnings call, in response to a question from a Barclays representative about what the company could do "to delay the process" if the FDA decided to withdraw Makena's approval, AMAG CEO Bill Heiden said, "If the FDA . . . pursue[d] a [withdrawal] path there would be a public hearing. And so there's some – there's time involved in preparing for that." Heiden further suggested AMAG could capitalize on the lack of safety concerns raised by the PROLONG Study to ensure a withdrawal decision "play[ed] out over a fairly lengthy . . . period of time."[66]

128. On November 16, 2020, Covis completed its acquisition of AMAG.

129. On December 4, 2020, Covis submitted its response to the withdrawal proposal with supporting data, analyses, and information. The response emphasized the "consistent and robust evidence of efficacy" from the Meis Study and criticized the PROLONG Study—the nine-year-long trial that AMAG has designed, implemented, and sponsored—for selection bias for "enroll[ing] far fewer Americans, and fewer American Black women in particular." It cited research and statistics showing that preterm birth disproportionately impacted black and other

[66] *AMAG Pharmaceuticals, Inc. (AMAG) CEO Bill Heiden on Q3 2019 Results – Earnings Call Transcript*, Seeking Alpha (Nov. 1, 2019), https://seekingalpha.com/article/4301526-amag-pharmaceuticals-inc-amag-ceo-bill-heiden-on-q3-2019-results-earnings-call-transcript.

minority women and socioeconomically disadvantaged populations and argued that withdrawing approval for Makena would "unfairly deprive an underserved and vulnerable patient population." Covis also cited the support of "key clinician groups, including ACOG, SMFM" in the wake of the 2019 BRUDAC meeting to support its argument that "withdraw[ing] Makena from the market without an opportunity for AMAG and the relevant medical and patient communities to be heard" would constitute "a serious violation of due process."[67]

130. AMAG and Covis also immediately mobilized to continue pushing a false narrative about Makena's efficacy. Indeed, while they were pushing back against the FDA's efforts to withdraw the drug, Defendants were conducting an aggressive campaign to continue to maximize profits before its inevitable withdrawal from the market. Defendants continued to publicly claim that Makena was effective at reducing the rate of preterm birth and make false and misleading statements and omissions about the drug's efficacy. For example, AMAG distributed a bilingual children's-type picture book in 2020 that said Makena would "help[] you get closer to term" and included no mention of the failed PROLONG Study.[68] Makena's website continued to emphasize to visitors that Makena "remains available" up until the drug's 2023 withdrawal hearing.[69]

131. In an effort to lessen the impact of the PROLONG Study—a randomized, controlled clinical trial for which AMAG itself was the Sponsor—AMAG and Covis proposed

[67] Submission of AMAG Pharmaceuticals, Inc. in Response to the FDA's Notice of Opportunity for a Hearing and Proposal to Withdraw Approval of Makena (Hydroxyprogesterone Caproate Injection) 250 mg/ml (NDA No.: NDA 21-945), Docket No. FDA-2020-N-2029 (Dec. 4, 2020), https://downloads.regulations.gov/FDA-2020-N-2029-0051/attachment_1.pdf.

[68] *Dear Baby: This is What I Will Do for You* Flipbook, Makena, https://makena.com/flipbook/index.html (last accessed Oct. 27, 2023)

[69] Sarah Karlin-Smith, *Accelerated Approval Reform Target? Makena Hearing Highlights Product Promotion During Withdrawal Period*, Pink Sheet (Nov. 1, 2022), https://pink.citeline.com/PS147249/Accelerated-Approval-Reform-Target-Makena-Hearing-Highlights-Product-Promotion-During-Withdrawal-Period.

follow-on studies. However, unlike PROLONG which was a randomized, double blind, controlled study, AMAG and Covis' proposed follow on studies included "a retrospective study using secondary real-world data sources" and "a prospective, primary data collection study."[70] Ultimately, Defendants decided to provide funding for an analysis of previously-performed studies, many of which involved drugs other than hydroxyprogesterone caproate, in an attempt to call into question the results of PROLONG and extend its sales of high-priced Makena.

132. On March 26, 2021, Covis announced the results of this meta-analysis it partially funded, called Evaluating Progestogens for Preventing Preterm birth International Collaborative ("EPPPIC"), claiming that it supported the effectiveness of Makena and that FDA should consider additional data before withdrawing the drug from the market. However, EPPPIC was merely a meta-analysis of individual participant data from randomized, controlled trials examining the effect of different uses of progesterone, including vaginal progesterone, intramuscular 17-hydroxyprogesterone caproate (17-OHPC), or oral progesterone. Many of the studies included in this analysis studied the effect of vaginal progesterone—not intramuscular hydroxyprogesterone caproate, like Makena. Others focused on different risk factors, such as a short cervix, as opposed to a history of preterm birth. Despite including data from thirty-one studies, only five compared the effect of hydroxyprogesterone caproate with a placebo in patients carrying a singleton pregnancy—the population for which Makena is approved.

133. Despite the inapposite nature of the studies included in the EPPPIC analysis, in order to support its continued claims of Makena's effectiveness and its continued marketing and sales of Makena, Defendants stated that the EPPPIC's "findings show that 17-OHPC and vaginal

[70] Press Release, Covis Pharma, AMAG Pharmaceuticals Files Submission in Response to the Food and Drug Administration's Notice of Opportunity for a Hearing and Proposal to Withdraw Approval of Makena® (Hydroxyprogesterone Caproate Injection) (Dec. 14, 2020), https://covispharma.com/index.php/press-release/.

progesterone both reduced birth before 34 weeks, by 17 percent and 22 percent respectively, with favorable reductions at <28 weeks and <37 weeks."[71]

134. Notably, two authors of the EPPPIC study reported receiving research funding from AMAG.

135. It is well established that financial ties between researchers and drug makers influences the results of the research, and industry-backed meta-analyses have been found to lack key indicators of methodological quality.

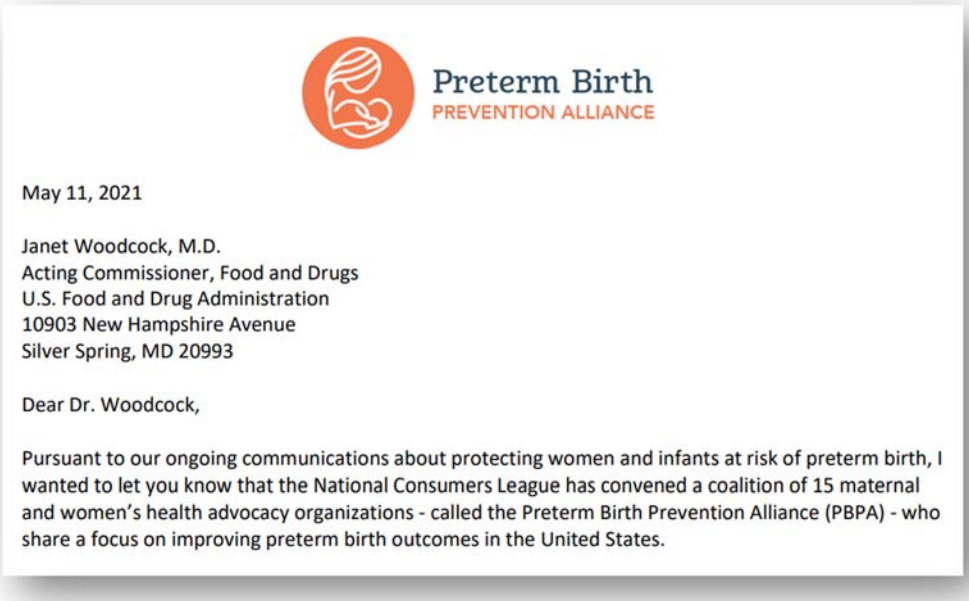
136. The FDA's Center for Drug Evaluation stated that "the publication of the EPPPIC meta-analysis does not change CDER's proposal to withdraw the approval of Makena."[72]

137. Beginning in or around April 20, 2021, Covis also funded an astroturf effort through the National Consumers League that called itself the "Preterm Birth Prevention Alliance," and whose stated goal was "Fighting to Protect 17P."[73] Deploying the same arguments as their funder, the group sought to cast doubt on the PROLONG Study and asserted that Makena was effective at preventing preterm birth. The "Alliance" and its members proceeded to lobby the FDA, members of Congress, and the White House's Domestic Policy Council and Gender Policy Council—without disclosing that Covis had created the group.

[71] Press Release, EPPPIC Study Reaffirms 17-OHPC for Reducing Early Preterm Birth in High-Risk, Singleton Pregnancies, Amag Pharmaceuticals, Inc. (Mar. 26, 2021), https://covispharma.com/index.php/press-release-2/.

[72] Press Release, Makena (Hydroxyprogesterone Caproate Injection) Information, FDA (Apr. 6, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information. (Apr. 6, 2023).

[73] *Preterm Birth Prevention Alliance*, Nat'l Consumer League, https://nclnet.org/pbp/ (last visited Oct. 11, 2023).



Preterm Birth
PREVENTION ALLIANCE

May 11, 2021

Janet Woodcock, M.D.
Acting Commissioner, Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock,

Pursuant to our ongoing communications about protecting women and infants at risk of preterm birth, I wanted to let you know that the National Consumers League has convened a coalition of 15 maternal and women's health advocacy organizations - called the Preterm Birth Prevention Alliance (PBPA) - who share a focus on improving preterm birth outcomes in the United States.

138. The Preterm Birth Prevention Alliance sought meetings with the FDA's Associate Commissioner for Women's Health and the Acting Commissioner for Food and Drugs, arguing that "additional data need to be generated to better understand which populations benefit the most from 17P."[74]

139. Together, Defendants and their network of covert, paid activists put pressure on the FDA to maintain Makena's approval, or at a minimum, delay its withdrawal so that Defendants could continue to reap significant profits during the Class Period through sales of the exorbitantly priced and ineffective drug. Covis then cited this bought-and-paid-for advocacy in its briefing materials to the FDA panel considering the CDER's recommendation to withdraw approval of Makena.

[74] Letter from Sally Greenberg, Preterm Birth Prevention Alliance, to Janet Woodcock, Acting Commissioner, FDA (May 11, 2021), https://downloads.regulations.gov/FDA-2020-N-2029-0066/attachment_1.pdf; Letter from Sally Greenberg, Preterm Birth Prevention Alliance, to Kaveeta Vasisht, Associate Commissioner for Women's Health, FDA (Dec. 10, 2021), https://downloads.regulations.gov/FDA-2020-N-2029-0085/attachment_1.pdf.

L. The FDA finally withdraws approval for Makena.

140. The hearing Defendants sought to delay the ultimate withdrawal of Makena from the market eventually took place over two years after it was requested by Defendants on October 17 to 19, 2022.

141. Those who spoke during the public comment period of the withdrawal hearing expressed frustration at Covis's "ruthless marketing" of the drug, even after the PROLONG Study results confirmed its ineffectiveness and the 2019 Advisory Committee had voted to revoke its marketing authorization, observing that Covis, "*who acquired the drug within days of the previous FDA vote[, is] maximizing [its] profits for whatever time remains*."[75]

142. Notably, in contrast to these testimonials from unbiased members of the public, several members of the Preterm Birth Prevention Alliance testified at the hearing in support of Defendants' position, urging the FDA to keep Makena on the market, including the National Consumers League, HealthyWomen, Miracle Babies, and Sidelines Nations Support Network. All of these organizations receive financial support from Covis.

143. On April 6, 2023, the FDA announced its final decision to withdraw approval of Makena.

144. The FDA explained that even "Covis conceded that the PROLONG trial failed to demonstrate clinical benefit."[76] It noted that "[t]he bottom line is that, based on current studies, there is an insufficient demonstration of effectiveness to balance any level of risk. Without a

[75] Sarah Karlin-Smith, *Accelerated Approval Reform Target? Makena Hearing Highlights Product Promotion During Withdrawal Period*, Pink Sheet (Nov. 1, 2022), https://pink.citeline.com/PS147249/Accelerated-Approval-Reform-Target-Makena-Hearing-Highlights-Product-Promotion-During-Withdrawal-Period.

[76] *Final Decision on the Proposal to Withdraw Approval of Makena Docket No. FDA-2020-N-2019*, FDA (Apr. 5, 2023), https://downloads.regulations.gov/FDA-2020-N-2029-0385/attachment_1.pdf.

favorable benefit-risk assessment, there is no justification for keeping the product on the market, even where there is an unmet need."[77]

M. Defendants engaged in mail and wire fraud.

145. Defendants' illegitimate scheme to sell more prescriptions of Makena at inflated prices constitutes mail and/or wire fraud in violation of 18 U.S.C. §§ 1341 and 1343.

146. To further the scheme to defraud, Defendants repeatedly concealed and failed to disclose the fact the Makena was ineffective at preventing preterm birth. Defendants also made false and misleading statements and omissions about the drug's efficacy.

147. The materials prepared by Defendants containing fraudulent and deceptive misstatements and omissions regarding Makena's efficacy included but were not limited to brochures, scripts promoted by Makena Care Connect, and statements on websites, all of which failed to disclose that Makena was not actually effective at preventing preterm birth.

148. Defendants knowingly made material misrepresentations and omissions about Makena's efficacy, falsely claiming that it reduced the rate of preterm birth for at risk patients and omitting that the drug lacked efficacy and was no better than placebo at preventing preterm birth.

149. Use of the mail and wires was an essential part of Defendants' scheme to defraud, and Defendants used them to disseminate their false and misleading misrepresentations and omissions about the drug's efficacy and to collect the proceeds from the fraudulently induced sales.

[77] *Id.*

150. Defendants also used the wires to transfer payments to fellow members of the Makena Promotion Enterprise, which was conducted to promote its fraudulent scheme, including third-party marketers and physicians.

N. Defendants' conduct harmed Plaintiff and members of the classes.

151. Plaintiff, members of the Classes, and members of the medical community reasonably relied on Defendants' representations regarding Makena's efficacy, and Defendants' failure to disclose the lack of support for such representations, when deciding to spend money covering prescriptions of Makena for their beneficiaries and/or write or obtain prescriptions.

152. Plaintiff and members of the Classes have paid millions of dollars for Makena that they would not have paid had Defendants disclosed that Makena lacked efficacy and had AMAG not fraudulently and misleadingly represented that Makena was effective at preventing preterm birth and fraudulently concealed information showing that Makena was, in fact, not effective at preventing preterm birth.

153. Plaintiff and members of the Classes included Makena on their formularies and paid for a worthless drug prescribed to their plan members when they would not have paid anything, or would have paid less, if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

V. FRAUDULENT CONCEALMENT AND TOLLING OF STATUTES OF LIMITATIONS

154. Defendants' fraudulent marketing scheme depended on concealing their knowledge about the ineffectiveness of Makena in preventing preterm birth. As the Collaborator and Sponsor of PROLONG and through communications with patients prescribed Makena through Makena Care Connection, Defendant had superior and exclusive knowledge regarding

Makena's lack of efficacy. Additionally, Defendants paid physicians and professional societies to make false and misleading statements and omissions regarding the effectiveness of the Makena and to cast doubt on contrary findings both before and after the publication of the PROLONG study. Plaintiff could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence.

155. The earliest Plaintiff could have reasonably become aware of the fraudulent marketing scheme was on April 6, 2023, when Makena was withdrawn from the market.

156. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. At all times, Defendants were under a continuous duty to disclose to Plaintiff and members of the Classes that Makena lacked efficacy and/or was no more effective than placebo at preventing preterm birth.

157. Plaintiff and members of the Classes have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiff and members of the Classes could not reasonably have discovered the fraudulent nature of Defendants' conduct. Accordingly, Defendants are estopped from relying on any statute of limitations to defeat any of the claims of Plaintiff and the members of the Classes.

VI. CLASS ACTION ALLEGATIONS

158. Plaintiff brings this action on behalf of itself and, under Federal Rule of Civil Procedure 23(a) and (b)(3), as a representative of a Class defined as follows:

> **Nationwide Class**: All entities in the United States who purchased, paid and/or provided reimbursement for some or all of the purchase price for Makena for consumption by their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period October 29, 2019 through April 6, 2023.
>
> **Ohio Subclass:** All entities in Ohio who purchased, paid and/or provided reimbursement for some or all of the purchase price for Makena for consumption by their members, employees, insureds,

participants, or beneficiaries, other than for resale, during the period October 29, 2019 through April 6, 2023.

Consumer Protection Subclass: All entities in Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, and Wisconsin who purchased, paid and/or provided reimbursement for some or all of the purchase price of Makena for consumption by their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period October 29, 2019 through April 6, 2023.

159. The Classes exclude Defendants and any entity in which Defendants have a controlling interest, as well as their officers, directors, legal representatives, successors, and assigns.

160. Plaintiff reserves the right to revise the definition of the Classes based upon subsequently discovered information and reserves the right to establish sub-classes where appropriate.

161. The Classes are each so numerous that joinder of all members is impracticable.

162. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Plaintiff knows of no difficulty to be encountered in the management of this litigation that would preclude its maintenance as a class action.

163. Plaintiff's claims are typical of the claims of the Classes Plaintiff seeks to represent. As alleged herein, Plaintiff and Class members sustained damages arising out of the same illegal actions and conduct by Defendant.

164. Common questions of law and fact exist to all members of the Classes and predominate over any issues solely affecting individual members of the Classes. The common and predominating questions of law and fact include, but are not limited to:

- Whether Defendants knew or should have known that Makena was ineffective at preventing preterm birth;
- Whether Defendants intentionally and knowingly falsely represented, concealed, suppressed and/or omitted material facts, including the fact that Makena was ineffective at preventing preterm birth;
- Whether Defendants made material misrepresentations and/or omissions concerning the efficacy of Makena;
- Whether members of the Classes would have included Makena on their formularies had Defendants not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth;
- Whether members of the Classes would have purchased, paid and/or provided reimbursement for some or all of the purchase price for Makena for consumption by their members, employees, insureds, participants, or beneficiaries, had Defendants not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth;
- Whether Defendants actively concealed and/or omitted material facts regarding Makena's efficacy, in order to, among other things, ensure more sales of Makena, sell Makena at a higher price, profit off a scheme to fraudulently market Makena as effective, and avoid the harm to its business and profits that would be caused by publicly disclosing the fact that Makena was not effective at preventing preterm birth;
- Whether Defendants conspired with third parties in furtherance of the unlawful acts alleged herein;
- Whether the scheme described between Defendants and its co-conspirators is an enterprise within the meaning of 18 U.S.C. § 1961(4);
- Whether Defendants' RICO Enterprise engaged in a pattern of racketeering activity;
- Whether Defendants conspired with others to violate 18 U.S.C. § 1962(c);
- Whether the scheme described among Defendants and their co-conspirators resulted in injury to Plaintiff and the members of the Classes; and
- Whether damages or other relief is warranted.

165. Plaintiff is willing and prepared to serve the Classes in a representative capacity with all the obligations and material duties necessary. Plaintiff will fairly and adequately represent and protect the interests of the Classes and has no interests adverse to or in conflict with the interests of any of the other members of the Classes.

166. Plaintiff's interests are co-extensive with and not antagonistic to those of absent members within the Classes. Plaintiff will undertake to represent and protect the interests of absent members within the Classes and will vigorously prosecute this action.

167. Plaintiff has engaged the services of the undersigned counsel. Counsel is experienced in complex litigation, will adequately prosecute this action, and will assert and protect the rights of, and otherwise represent, Plaintiff and absent members of the Classes.

168. Class action status is warranted under Rule 23(b)(3) because questions of law or fact common to the members of the Classes predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

169. The interest of members within the Classes in individually controlling the prosecution of separate actions is theoretical and not practical. The Classes have a high degree of similarity and are cohesive, and Plaintiff anticipates no difficulty in the management of this matter as a class action.

170. The nature of notice to the proposed Classes is contemplated to be by direct mail upon certification of the Classes, or, if such notice is not practicable, by the best notice practicable under the circumstances including, amongst other things, email, publication in major newspapers, and the internet.

VII. CLAIMS FOR RELIEF

COUNT ONE - VIOLATION OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1962(c)
On behalf of Plaintiff and the Nationwide Class

171. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

172. Plaintiff brings this claim on behalf of itself and the Nationwide Class.

173. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of an enterprise, the Makena Promotion Enterprise, through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

174. The Makena Promotion Enterprise is an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4), consisting of: (i) Defendants, including their employees and agents; (ii) its external marketing firms, including, but not limited to, the CDM Group, AllCare Plus Pharmacy, LLC, and PPD Medical Communications; (iii) the network of doctors AMAG paid to promote Makena; and (iv) the professional associations (including, but not limited to, ACOG and SMFM) AMAG supported to ensure institutional support for prescribing Makena; and (v) the consumer groups Covis funded to echo its fraudulent misstatements and omissions about the efficacy of Makena and to lobby the FDA and other government entities to prevent, or at least delay, the withdrawal of Makena from the market. The Makena Promotion Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. The members of the enterprise are all "persons" within the meaning of 18 U.S.C. § 1961(3) and are distinct from the Makena Promotion Enterprise.

175. The Makena Promotion Enterprise fits within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" that created and maintained systematic links for a common purpose: to sell as many units of Makena as possible—by, *inter alia*, increasing the number of

prescriptions of hydroxyprogesterone caproate and ensuring such prescriptions resulted in pharmacies dispensing name-brand Makena, seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible after the results of the PROLONG study provided conclusive evidence that Makena is ineffective at preventing preterm birth, and redoubling efforts to promote sales of Makena during its extended time on the market —thereby maximizing the revenue and profitability of the Makena Promotion Enterprise's members

176. Defendants have conducted and participated in the affairs of the Makena Promotion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343.

177. For Defendants, the purpose of the scheme to defraud was to conceal the fact that Makena was ineffective at preventing preterm birth and to keep Makena on the market as long as possible in order to sell at many prescriptions of Makena at the highest possible prices before the drug was withdrawn.

178. As detailed in the factual allegations above, Defendants were well aware of the fact that Makena was ineffective at preventing preterm birth for years and received conclusive proof of this fact after the PROLONG study results were released. Defendants nevertheless chose to aggressively market Makena in an effort to have Makena included on Plaintiff and Nationwide Class members' formularies and to sell as many prescriptions of Makena as possible. Indeed, even when faced with the PROLONG study results conclusively demonstrating Makena's ineffectiveness at preventing preterm birth, Defendants redoubled their efforts to market and promote Makena as a drug that was effective at preventing preterm birth and sought to prevent, or at least delay, the FDA's withdrawal of Makena from the market.

179. The Makena Promotion Enterprise members were crucial to Defendants perpetuating this scheme as they, *inter alia,* targeted patients, healthcare providers, and third-party payors to increase the number of prescriptions of Makena and to ensure coverage and payment of such prescriptions, echoed and promoted Defendants' fraudulent misrepresentations and/or omissions regarding the efficacy of Makena and assisted in Defendants' efforts to prevent, or at least delay, the withdrawal of Makena from the market.

180. To carry out their scheme to defraud, Defendants participated in the Makena Promotion Enterprise through various acts of racketing activity that employed the use of mail and wire facilities in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud). These instances of mail and wire fraud included preparing brochures, scripts, and statements made on websites which were used by members of the Makena Promotion Enterprise to perpetuate the fraudulent promotion of Makena as effective at preventing preterm birth.

181. The Makena Promotion Enterprise engaged in and affected interstate commerce, because, *inter alia*, it made false and misleading statements and omissions while marketing a drug that was prescribed to thousands of individuals throughout the United States, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

182. Defendants exerted control over the Makena Promotion Enterprise, and participated in the operation or management of the affairs of the Makena Promotion Enterprise, by directing the conduct of the third-party marketers, maintaining a paid network of doctors and hospitals to promote Makena as effective when it was not, strategically courting professional associations (including, but not limited to, ACOG and SMFM) to include false and misleading statements and omissions regarding Makena in their practice materials, and creating astroturf

"advocacy" groups to create the false impression that entities other than Defendants continued to believe in the efficacy of Makena after the announcement of the PROLONG study results.

183. As detailed above, Defendants' fraudulent scheme consisted of making false and misleading statements and omissions regarding the efficacy of Makena while possessing and concealing knowledge that the drug is not effective at preventing preterm birth and attempting to delay the eventual withdrawal of Makena from the market in order to continue profiting off of sales of the drug for as long as possible after the PROLONG study definitively showed that Makena is ineffective at preventing preterm birth. In furtherance of this scheme, Defendants facilitated the creation of an elaborate marketing operation aimed at convincing: doctors to prescribe the drug; patients to take, or continue to take, the drug; and third-party payors to include the drug on their formularies and cover the drug's exorbitant costs. Defendants also maintained a network of doctors to promote the use of Makena to prevent preterm birth to both physicians and patients. Beyond its relationships with individual doctors, Defendants targeted professional associations of obstetricians (including, but not limited to, ACOG and SMFM) to ensure false and misleading statements and omissions regarding the efficacy of Makena were in the organizations' practice materials. Moreover, once Defendants knew about the results of the PROLONG study which showed Makena is ineffective at preventing preterm birth, in addition to continuing its previous efforts to promote sales of the worthless drug, Defendants also created deceptive "advocacy" groups to echo Defendants' own fraudulent misstatements and omissions about the efficacy of Makena and to lobby for the continuation of Makena on the market.

184. The scheme devised and implemented by Defendants, as well as other members of the Makena Promotion Enterprise, amounted to a common course of conduct with a common purpose intended to fraudulently increase sales of Makena at exorbitant prices and thereby

maximize the revenue, profitability and/or funding sources of the Makena Promotion Enterprise members.

185. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and members of the Nationwide Class.

186. The pattern of racketeering activity alleged herein and the Makena Promotion Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Makena Promotion Enterprise.

187. As a result of Defendants' and members of the Makena Promotion Enterprise's fraudulent activities, thousands of patients were prescribed an exorbitantly priced drug that is not effective at preventing preterm birth.

188. Plaintiff and members of the Nationwide Class have been injured in their business and property by reason of Defendants' fraudulent scheme and the success of the Makena Promotion Enterprise. Plaintiff and members of the Nationwide Class included Makena on their formularies and have paid millions of dollars for a drug prescribed to their plan members that they would not have paid for, or would have paid less for, in the absence of the fraudulent course of conduct underlying the Makena Promotion Enterprise which included misrepresentations and/or omissions regarding the efficacy of Makena and the failure to disclose that Makena was ineffective at preventing preterm birth.

189. The injuries of Plaintiff and members of the Nationwide Class were proximately caused by Defendants' racketeering activity. But for the misrepresentations and omissions made by Defendants and members of the Makena Promotion Enterprise, Plaintiff and members of the

Nationwide Class would not have included Makena on their formularies and thousands of prescriptions for Makena would not have been paid for (or would have been paid less for) by Plaintiff and Nationwide Class members.

190. Plaintiff's and the Nationwide Class's injuries were directly caused by Defendants' racketeering activity. By making material misrepresentations and omissions regarding Makena's efficacy and/or by failing to disclose that Makena is ineffective at preventing preterm birth, Defendants directly caused Plaintiff and Nationwide Class members to include Makena on their formularies and to pay for Makena prescriptions given to their plan members that they would not have paid for or would have paid less for.

191. Plaintiff and Nationwide Class members were directly harmed by this unlawful conduct, and there is no other plaintiff or class of plaintiffs better situated to seek a remedy for the economic harms of Defendants' fraudulent scheme.

192. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiff and Nationwide Class members for three times the damages they have sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT TWO - VIOLATION OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1962(d)
On behalf of Plaintiff and the Nationwide Class

193. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

194. Plaintiff brings this claim on behalf of itself and the Nationwide Class.

195. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

196. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been to conduct or participate in, directly or indirectly, the

affairs of the § 1962(c) Makena Promotion Enterprise, described previously, through a pattern of racketeering activity.

197. As demonstrated in detail above, Defendants and members of the Makena Promotion Enterprise have engaged in overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including by making material misrepresentations and omissions designed to permit Defendants to benefit financially from sales of Makena.

198. Over the course of several years Defendants and their Makena Promotion Enterprise coconspirators shared information relevant to their fraudulent scheme to sell as many prescriptions of Makena as possible and to keep Makena on the market as long as possible. The Defendants and the Makena Promotion Enterprise members' close cooperation on issues surrounding the sale and promotion of Makena and efforts to prevent and/or delay the withdrawal of Makena from the market, their misstatements and/or omissions regarding the efficacy of Makena at preventing preterm birth and their joint participation in multiple predicate acts is evidence of the conspiracy to commit at least two racketeering predicate acts.

199. Defendants and members of the Makena Promotion Enterprise committed a series of overt acts in furtherance of the conspiracy and to affect the objects thereof. Specifically, Defendants and their coconspirators made misrepresentations and/or omissions regarding the efficacy of Makena at preventing preterm birth even after the conclusive results of the PROLONG study demonstrated that Makena was no better than a placebo. Moreover, Defendants and coconspirators sought to prevent, or at least delay as long as possible, the withdrawal of Makena from the market after the conclusive PROLONG study results, which showed Makena is ineffective at preventing preterm birth, were known to Defendants.

200. These efforts to perpetuate their fraudulent scheme included the targeting of patients and prescribers to seek out Makena and direct efforts to encourage third-party payors to provide coverage for Makena.

201. The nature of Defendants' and members of the Makena Promotion Enterprise's fraudulent acts and material misrepresentations and omissions, in furtherance of the conspiracy, gives rise to an inference that they not only agreed to the objective of a RICO enterprise by conspiring to violate 18 U.S.C. § 1962(c), but also that they were, and are, aware that their fraudulent acts have been and are part of an overall pattern of racketeering activity.

202. As a direct and proximate result of Defendants' and members of the Makena Promotion Enterprise's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and Nationwide Class members have been injured in their business or property, as set forth more fully above. Plaintiff and members of the Nationwide Class would not have included Makena on their formularies and would not have paid for, or would have paid less for, Makena prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing pre-term birth.

203. Defendants have sought to engage in, and has engaged in, the commission of overt acts, including the following unlawful racketeering predicate acts: (i) multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346; and (ii) multiple instances of wire fraud in violation of 18 U.S.C. §§ 1343 and 1346.

COUNT THREE – VIOLATION OF THE OHIO CONSUMER SALES PRACTICES ACT ("OHIO CSPA"), Ohio Rev. Code § 1345.01, *et seq.*
On behalf of Plaintiff and the Ohio Subclass

204. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

205. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Ohio Subclass.

206. Defendants are "suppliers" as that term is defined in Ohio Rev. Code § 1345.01(C).

207. Plaintiff and Ohio Subclass members are "consumers" as that term is defined in Ohio Rev. Code § 1345.01(D).

208. The relevant health plan payments for Makena are "consumer transaction[s]" within the meaning of Ohio Rev. Code § 1345.01(A).

209. The Ohio CSPA broadly prohibits "unfair or deceptive act[s] or practice[s] in connection with a consumer transaction." Ohio Rev. Code § 1345.02.

210. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

211. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Ohio Subclass members.

212. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Ohio CSPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

213. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

214. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Ohio Subclass, about the true efficacy of Makena.

215. Defendants knew or should have known that their conduct violated the Ohio CSPA.

216. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

217. Defendants intended that Plaintiff and members of the Ohio Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

218. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Ohio Subclass members in that Plaintiff and Ohio Subclass members

would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

219. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Ohio Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

220. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Ohio Subclass.

221. Plaintiff and members of the Ohio Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Ohio Subclass did not (and could not) unravel Defendants' deception on their own.

222. The facts concealed and omitted by Defendants from Plaintiff and members of the Ohio Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Ohio Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if

Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

223. Plaintiff and members of the Ohio Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

224. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

225. As a result of Defendants' wrongful conduct, Ohio Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Ohio Rev. Code § 1345.09, *et seq.*

COUNT FOUR – VIOLATION OF THE OHIO DECEPTIVE TRADE PRACTICES ACT ("OHIO DTPA"), Ohio Rev. Code § 4165, *et seq.*
On behalf of Plaintiff and the Ohio Subclass

226. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

227. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Ohio Subclass.

228. The Ohio DTPA prohibits "deceptive trade practices," which includes: "[r]epresent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval,

status, affiliation, or connection that the person does not have" and "[r]epresent[ing] that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another."

229. Defendants, Plaintiff, and Subclass members are "persons" within the meaning of Ohio Rev. Code § 4165.01(D).

230. Defendants' conduct with respect to the marketing of Makena, as described in this Complaint, constitutes deceptive trade practices in violation of the Ohio DTPA.

231. In violation of the Ohio DTPA, Defendants employed unfair, unlawful and deceptive acts or practices, fraud, false pretense, misrepresentations, and/or concealment, suppression or omission of material facts with the intent that their target audience of patients, prescribers and third-party payors rely on such misrepresentation, concealment, suppression or omission in connection with the sale of Makena. Defendants knowingly misrepresented, concealed, suppressed and/or omitted material facts regarding Makena which directly caused harm to Plaintiff and members of the Ohio Subclass.

232. Defendants knew that Makena was ineffective at treating preterm birth for years and yet failed to disclose and actively concealed that fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

233. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Ohio Subclass members.

234. Defendants continued efforts to create the impression that Makena is effective at treating preterm birth despite knowledge to the contrary constituted false and/or misleading statements about Makena in violation of the Ohio DTPA.

235. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

236. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in patients, prescribers and third-party payors which were the target audience of Defendants false and/or misleading statements, and were likely to and did in fact deceive reasonable consumers, including the members of the Ohio Subclass, about the true efficacy of Makena.

237. Defendants intended that Plaintiff and members of the Ohio Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

238. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Ohio Subclass members in that Plaintiff and Ohio Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had

not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

239. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Ohio Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

240. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Ohio Subclass.

241. The facts concealed and omitted by Defendants from Plaintiff and members of the Ohio Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Ohio Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

242. Plaintiff and members of the Ohio Subclass suffered ascertainable loss proximately caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena

on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

243. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

244. As a result of Defendants' wrongful conduct, Ohio Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual damages and reasonable attorneys' fees, pursuant to Ohio Rev. Code § 4165.03.

COUNT FIVE – VIOLATION OF THE ARIZONA CONSUMER FRAUD ACT ("ARIZONA CFA"), Ariz. Rev. Stat. § 44-1521, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

245. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

246. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

247. The Arizona CFA provides that "[t]he act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice."

248. Defendants, Plaintiff, and Class members are "persons" within the meaning of Ariz. Rev. Stat. § 44-1521(6).

249. Each Makena prescription is "merchandise" within the meaning of Ariz. Rev. Stat. § 44-1521(5).

250. Defendants' conduct, as set forth above, occurred in the conduct of trade or commerce.

251. As alleged in this Complaint, Defendants have employed "deception," "fraud, false pretense, false promise, misrepresentation, [and/]or concealment" with respect to their marketing of Makena.

252. Defendants' conduct, as described in this Complaint, also constitutes "unfair act[s]."

253. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

254. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

255. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Arizona CFA by engaging in acts or practices which are otherwise unfair, misleading, false, or deceptive to the consumer.

256. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

257. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

258. Defendants knew or should have known that their conduct violated the Arizona CFA.

259. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

260. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

261. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan

members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

262. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

263. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

264. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

265. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

266. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

267. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

268. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees.

COUNT SIX – VIOLATION OF THE ARKANSAS DECEPTIVE TRADE PRACTICES ACT ("ARKANSAS DTPA"), Ark. Code § 4-88-101, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

269. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

270. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

271. The Arkansas DTPA prohibits "[d]eceptive and unconscionable trade practices," which include, but are not limited to, "[e]ngaging in any . . . unconscionable, false, or deceptive act or practice in business, commerce, or trade." The statute further bars, in connection with the

sale or advertisement of any goods, "(1) the act, use, or employment by any person of any deception, fraud, or pretense; or (2) the concealment, suppression, or omission of any material fact with intent that other rely upon the concealment, suppression, or omission."

272. Defendants, Plaintiff, and Class members are "persons" within the meaning of Ark. Code § 4-88-102(5).

273. Each Makena prescription constitutes "goods" within the meaning of Ark. Code § 4-88102(4).

274. As alleged in this Complaint, Defendants' conduct with respect to the marketing of Makena constitutes both "unconscionable" and "deceptive" acts in violation of the Arkansas DTPA.

275. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

276. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

277. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Arkansas DTPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

278. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

279. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

280. Defendants knew or should have known that their conduct violated the Arkansas DTPA.

281. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

282. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

283. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan

members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

284. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

285. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

286. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

287. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

288. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

289. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

290. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Ark. Code. § 4-88-113(f).

COUNT SEVEN – VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW ("UCL"), Cal. Bus. & Prof. Code § 17200, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

291. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

292. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

293. The UCL prohibits "unlawful, unfair, or fraudulent business acts or practices."

294. Defendants violated the "unlawful" prong of § 17200 through their marketing of Makena, as described throughout this Complaint.

295. Defendants also violated the "fraudulent" prong of § 17200 through their marketing of Makena, as described throughout this Complaint.

296. In addition, Defendants violated the "unfair" prong of § 17200 because Defendants' acts and practices described in this Complaint caused Defendants to profit at the expense of Plaintiff and Class members.

297. The California courts have set out several definitions of unfairness. Defendants' conduct is unfair under each of them:

a. "[T]he consumer injury is substantial, is not outweighed by any countervailing benefits to consumers or to competition, and is not an injury the consumers themselves could reasonably have avoided."[78]

b. Defendants' conduct "offends an established public policy [the FTC Policy Statement on Unfairness] or is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers."[79]

c. Plaintiff's claim is predicated upon public policy which is "'tethered' to specific constitutional, statutory or regulatory provisions."[80]

298. Defendants' actions, as set forth above, occurred within the conduct of their business and in trade or commerce.

299. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at

[78] *See Daugherty v. Am. Honda Motor Co.*, 144 Cal. App. 4th 824, 839 (2006).

[79] *See West v. JPMorgan Chase Bank, N.A.*, 214 Cal. App. 4th 780, 806 (2013) (quoting *Smith v. State Farm Mut. Auto. Ins. Co.*, 93 Cal. App. 4th 700, 719 (2001)).

[80] *See West*, 214 Cal. App. at 806 (quoting *Scripps Clinic v. Superior Court*, 108 Cal. App. 4th 917, 940 (2003)).

preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

300. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

301. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the UCL by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

302. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

303. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

304. Defendants knew or should have known that their conduct violated the UCL.

305. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

306. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

307. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

308. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

309. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

310. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

311. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

312. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

313. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

314. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Cal. Bus. & Prof. Code § 17203, Cal. Civ. Proc. Code § 384, Cal. Civ. Proc. Code § 1021.5, and Cal. Civ. Code § 3345.

COUNT EIGHT – VIOLATION OF THE COLORADO CONSUMER PROTECTION ACT ("COLORADO CPA"), Colo. Rev. Stat. § 6-1-101, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

315. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

316. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

317. The Colorado CPA prohibits deceptive practices in the course of a person's business including, but not limited to: "knowingly or recklessly mak[ing] a false representation as to the characteristics, ingredients, uses, benefits, alterations, or quantities of goods, food, services, or property or a false representation as to the sponsorship, approval, status, affiliation, or connection of a person therewith;" "[r]epresent[ing] that goods, food, services, or property are of a particular standard, quality, or grade, or that goods are of a particular style or model, if he knows or should know that they are of another;" and "Fail[ing] to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction."

318. Each Defendant is a "person" under Colo. Rev. Stat. § 6-1-102(6).

319. Plaintiff and Subclass members are "consumers" for purposes of Colo. Rev. Stat. § 6-1-113(1)(a).

320. Each Defendant's conduct, as set forth above, occurred in the conduct or trade or commerce.

321. As alleged in this Complaint, Defendants' conduct with respect to the marketing of Makena constitutes: "knowingly or recklessly mak[ing] a false representation as to the

characteristics, ingredients, uses, benefits, alterations, or quantities of goods, food, services, or property or a false representation as to the sponsorship, approval, status, affiliation, or connection of a person therewith;" "[r]epresent[ing] that goods, food, services, or property are of a particular standard, quality, or grade, or that goods are of a particular style or model, if he knows or should know that they are of another;" and "Fail[ing] to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction" in violation of the Colorado CPA.

322. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

323. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

324. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Colorado CPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

325. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the

deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

326. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

327. Defendants knew or should have known that their conduct violated the Colorado CPA.

328. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

329. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

330. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

331. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

332. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

333. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

334. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

335. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

336. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Colo. Rev. Stat. § 6-1-113.

COUNT NINE – VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT ("CONNECTICUT UTPA"), Conn. Gen. Stat. § 42-110A, *et seq.*

337. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

338. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

339. The Connecticut UTPA provides: "No person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

340. Each Defendant is a "person" within the meaning of Conn. Gen. Stat. § 42-110a(3).

341. Defendants' challenged conduct occurred in "trade" or "commerce" within the meaning of Conn. Gen. Stat. § 42-110a(4).

342. As alleged in this Complaint, Defendants' conduct with respect to the marketing of Makena constitutes both "unfair" and "deceptive" acts in violation of the Connecticut UTPA.

343. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

344. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

345. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Connecticut UTPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

346. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

347. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

348. Defendants knew or should have known that their conduct violated the Connecticut UTPA.

349. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

350. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

351. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

352. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that

Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

353. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

354. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

355. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

356. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on

their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

357. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

358. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Conn. Gen. Stat. § 42-110g.

COUNT TEN – VIOLATION OF THE DELAWARE CONSUMER FRAUD ACT ("DELAWARE CFA"), Del. Code Tit. 6 § 2513, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

359. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

360. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

361. The Delaware CFA prohibits the "act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby."

362. Each Defendant is a "person" within the meaning of Del. Code tit. 6, § 2511(7).

363. Defendants' actions, as set forth above, occurred in the conduct of trade or commerce.

364. As alleged in this Complaint, Defendants' conduct with respect to the marketing of Makena violated the Delaware CFA.

365. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

366. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

367. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Delaware CFA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

368. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

369. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable

consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

370. Defendants knew or should have known that their conduct violated the Delaware CFA.

371. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

372. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

373. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

374. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

375. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

376. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

377. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

378. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

379. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

380. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees.

COUNT ELEVEN – VIOLATION OF THE DISTRICT OF COLUMBIA CONSUMER PROTECTION PROCEDURES ACT ("D.C. CPPA"), D.C. Code § 28-3901, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

381. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

382. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

383. Defendants are "merchants" as that term is defined in D.C. Code § 28- 3901(a)(3).

384. Plaintiff and Consumer Protection Subclass members are "consumers" as that term is defined in D.C. Code § 28- 3901(1)(2).

385. The relevant health plan payments were for Makena, which is a "good or service" as that term is defined in D.C. Code § 28- 3901(a)(7).

386. The D.C. CPPA broadly provides that "[i]t shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice, whether or not any consumer is in fact misled, deceived, or damaged thereby," D.C. Code § 28-3904.

387. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at

preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

388. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

389. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the D.C. CPPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

390. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

391. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

392. Defendants knew or should have known that their conduct violated the D.C. CPPA.

393. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

394. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

395. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

396. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

397. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

398. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that

Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

399. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

400. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

401. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

402. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to D.C. Code § 28-3901.

COUNT TWELVE – VIOLATION OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT ("FDUTPA"), Fla. Stat. § 501.201, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

403. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

404. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

405. The FDUTPA prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce."

406. In outlawing unfair acts or practices, the Florida Legislature adopted the FTC's interpretations of § 5(a)(1) of the Federal Trade Commission Act. The Legislature specifically stated that a violation of FDUTPA "may be based upon . . . [t]he standards of unfairness . . . set forth and interpreted by the Federal Trade Commission or the federal courts."

407. Defendants' conduct, as described in this Complaint, constitutes "deceptive acts" in violation of the FDUTPA.

408. In addition, Defendants' conduct, as described in this Complaint, constitutes "unfair" acts in violation of the FDUTPA.

409. Plaintiff and Class members are "consumers" within the meaning of Fla. Stat. § 501.203(7).

410. Each Defendant engaged in "trade or commerce" within the meaning of Fla. Stat. § 501.203(8).

411. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at

preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

412. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

413. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the FDUTPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

414. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

415. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

416. Defendants knew or should have known that their conduct violated the FDUTPA.

417. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

418. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

419. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

420. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

421. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

422. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

423. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

424. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

425. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

426. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Fla. Stat. §§ 501.211(1)-(2), 501.2105(1).

COUNT THIRTEEN – VIOLATION OF THE GEORGIA FAIR BUSINESS PRACTICES ACT ("GEORGIA FBPA"), Ga. Code § 10-1-390, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

427. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

428. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

429. The Georgia FBPA provides that "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce are declared unlawful." This prohibition includes, but is not limited to: "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have" and "[r]epresenting that goods or services are of a particular standard, quality, or grade or that goods are of a particular style or model, if they are of another."

430. Defendants, Plaintiff, and Subclass members are "persons" within the meaning of Ga. Code § 10-1-392(a)(24).

431. The relevant purchases of Makena prescriptions were "consumer transactions" within the meaning of Ga. Code § 10-1-392(a)(10).

432. Defendants' conduct relating to the marketing of Makena constitutes "consumer acts or practices" within the meaning of Ga. Code § 10-1-392(a)(7).

433. Defendants' conduct relating to the marketing of Makena, as described in this Complaint, constituted unfair or deceptive acts or practices in violation of the Georgia FBPA.

434. Plaintiff and Subclass members have suffered injury or damages as a result of Defendants' violations of the Georgia FBPA.

435. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

436. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

437. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Georgia FBPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

438. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

439. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

440. Defendants knew or should have known that their conduct violated the Georgia FBPA.

441. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

442. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

443. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

444. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

445. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

446. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

447. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

448. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

449. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

450. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and

proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Ga. Code § 10-1-399.

COUNT FOURTEEN – VIOLATION OF THE HAWAII UNFAIR AND DECEPTIVE ACTS OR TRADE PRACTICES ACT ("HAWAII UDAP"), Haw. Rev. Stat. § 480, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

451. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

452. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

453. The Hawaii UDAP provides that "[u]nfair methods of competition . . . in the conduct of any trade or commerce are unlawful."

454. It further provides that "[a]ny person may bring an action based on unfair methods of competition declared unlawful by this section."

455. Defendants, Plaintiff, and Subclass members are "persons" under Haw. Rev. Stat. § 480-1.

456. As alleged in this Complaint, Defendants have engaged in unfair methods of competition under Haw. Rev. Stat. § 480-2(e).

457. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

458. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

459. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Hawaii UDAP by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

460. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

461. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

462. Defendants knew or should have known that their conduct violated the Hawaii UDAP.

463. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

464. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and

expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

465. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

466. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

467. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

468. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

469. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered

them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

470. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

471. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

472. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Haw. Rev. Stat. § 480-13.

COUNT FIFTEEN – VIOLATION OF THE IDAHO CONSUMER PROTECTION ACT ("IDAHO CPA"), Idaho Code § 48-601, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

473. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

474. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

475. The Idaho CPA prohibits "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce," including, but not limited to: "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, connection, qualifications or license that he does not have;" "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;" "[d]isparaging the goods, services, or business of another by false or misleading representation of fact;" and "[e]ngaging in any act or practice that is otherwise misleading, false, or deceptive to the consumer."

476. Each Defendant is a "person" under Idaho Code Ann. § 48-602(1).

477. Defendants' acts or practices as set forth above occurred in the conduct of "trade" or "commerce" under Idaho Code Ann. § 48-602(2).

478. As alleged in this Complaint, Defendants' conduct with respect to the marketing of Makena constitutes both "unfair" and "deceptive" acts under the Idaho CPA.

479. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

480. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

481. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Idaho CPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

482. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

483. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

484. Defendants knew or should have known that their conduct violated the Idaho CPA.

485. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

486. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and

expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

487. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

488. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

489. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

490. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

491. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered

them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

492. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

493. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

494. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Idaho Code § 48-608.

COUNT SIXTEEN – VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT ("ICFA"), 815 Ill. Comp. Stat. Ann. § 505/10A, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

495. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

496. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

497. ICFA prohibits "unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact . . . in the conduct of any trade or commerce . . . whether any person has in fact been misled, deceived or damaged thereby."

498. That section also provides: "In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5(a) of the Federal Trade Commission Act."

499. Each Defendant is a "person" as that term is defined in 815 Ill. Comp. Stat. § 505/1(c).

500. Plaintiff and Subclass members are "consumers" as that term is defined in 815 Ill. Comp. Stat. § 505/1(e).

501. Defendants' conduct, as described in this Complaint, constitutes "deceptive acts" in violation of the ICFA.

502. In addition, Defendants' conduct, as described in this Complaint, constitutes "unfair" acts in violation of the ICFA.

503. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients,

and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

504. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

505. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the ICFA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

506. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

507. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

508. Defendants knew or should have known that their conduct violated the ICFA.

509. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

510. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

511. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

512. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

513. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

514. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

515. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

516. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

517. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

518. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to 815 Ill. Comp. Stat. § 505/10a.

COUNT SEVENTEEN – VIOLATION OF THE LOUISIANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW ("LOUISIANA CPL"), La. Rev. Stat. § 51:1401, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

519. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

520. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

521. The Louisiana CPL makes unlawful "unfair or deceptive acts or practices in the conduct of any trade or commerce."

522. Defendants, Plaintiff, and Subclass members are "persons" within the meaning of La. Rev. Stat. § 51:1402(8).

523. Plaintiff and Subclass members are "consumers" within the meaning of La. Rev. Stat. § 51:1402(1).

524. Defendants' conduct, as described in this Complaint, constitutes both "deceptive" and "unfair" practices in violation of the Louisiana CPL.

525. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

526. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

527. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Louisiana CPL by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

528. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

529. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

530. Defendants knew or should have known that their conduct violated the Louisiana CPL.

531. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

532. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

533. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

534. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

535. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

536. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

537. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer

Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

538. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

539. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

540. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to La. Rev. Stat. § 51:1409.

COUNT EIGHTEEN – VIOLATION OF THE MARYLAND CONSUMER PROTECTION ACT ("MARYLAND CPA"), Md. Code, Com. Law § 13-101, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

541. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

542. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

543. The Maryland CPA provides that a person may not engage in any unfair or deceptive trade practice, including: "False, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers"; "Failure to state a material fact if the failure deceives or tends to deceive"; and "Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same." The statute further provides that a person may not engage in such conduct regardless of whether the consumer is actually deceived or damaged.

544. Defendants, Plaintiff, and Class members are "persons" within the meaning of Md. Code, Com. Law § 13-101(h).

545. Defendants' conduct, as described in this Complaint, constitutes both "deceptive" and "unfair" acts or practices in violation of the Maryland CPA.

546. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

547. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

548. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and

unfair acts prohibited by the Maryland CPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

549. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

550. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

551. Defendants knew or should have known that their conduct violated the Maryland CPA.

552. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

553. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

554. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would

not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

555. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

556. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

557. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

558. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

559. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

560. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

561. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Md. Code, Com. Law §§ 13-406, 13-408.

COUNT NINETEEN – VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT ("MASSACHUSETTS CPA"), Mass. Gen. Laws. Ch. 93A § 1, *et seq.* On behalf of Plaintiff and the Nationwide Class or alternatively on behalf of the Consumer Protection Subclass

562. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

563. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

564. The Massachusetts CPA provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

565. Defendants, Plaintiff, and Subclass members are "persons" within the meaning of Mass. Gen. Laws § 1(a).

566. Defendants, Plaintiff, and Subclass members are engaged in "trade and commerce" within the meaning of Mass. Gen. Laws § 1(b).

567. Defendants' conduct, as described in this Complaint, constitutes both "unfair methods of competition" and "unfair or deceptive acts or practices" in violation of the Massachusetts CPA.

568. Plaintiff and Subclass members have suffered a loss of money or property as a result of Defendants' use of an unfair method of competition or unfair or deceptive acts or practices.

569. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

570. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

571. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Massachusetts CPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

572. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

573. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

574. Defendants knew or should have known that their conduct violated the Massachusetts CPA.

575. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

576. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

577. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan

members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

578. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

579. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

580. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

581. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

582. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

583. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

584. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Mass. Gen. Laws ch. 93A § 11.

COUNT TWENTY – VIOLATION OF THE MICHIGAN CONSUMER PROTECTION ACT ("MICHIGAN CPA"), Mich. Comp. Laws § 445.902, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

585. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

586. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

587. The Michigan CPA prohibits "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce," including: "[f]ailing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not

reasonably be known by the consumer"; "[m]aking a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is"; and "[f]ailing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner."

588. Plaintiff and Class members are "person[s]" within the meaning of the Mich. Comp. Laws § 445.902(1)(d).

589. Each Defendant is a "person" engaged in "trade or commerce" within the meaning of the Mich. Comp. Laws § 445.902(1)(d) and (g).

590. Defendants' conduct, as described in this Complaint, constitutes both "deceptive" and "unfair" acts or practices in violation of the Michigan CPA.

591. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

592. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

593. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Michigan CPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

594. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

595. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

596. Defendants knew or should have known that their conduct violated the Michigan CPA.

597. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

598. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

599. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan

members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

600. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

601. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

602. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

603. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

604. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

605. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

606. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Mich. Comp. Laws § 445.911.

COUNT TWENTY ONE – VIOLATION OF THE MINNESOTA CONSUMER FRAUD ACT ("MINNESOTA CFA"), Minn. Stat. § 325F.68, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

607. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

608. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

609. The Minnesota CFA prohibits "[t]he act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive

practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby."

610. Each purchase of analog insulin constitutes "merchandise" within the meaning of Minn. Stat. § 325F.68(2).

611. Defendants' conduct, as described in this Complaint, constitutes "deceptive" acts or practices in violation of the Minnesota CFA.

612. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

613. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

614. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Minnesota CFA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

615. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing

preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

616. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

617. Defendants knew or should have known that their conduct violated the Minnesota CFA.

618. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

619. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

620. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

621. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to

effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

622. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

623. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

624. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

625. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that

Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

626. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

627. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Minn. Stat. §§ 8.31(3a); 549.20(1)(a).

COUNT TWENTY TWO – VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT ("MISSOURI MPA"), Mo. Rev. Stat. § 407.010, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

628. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

629. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

630. The Missouri MPA makes unlawful the "act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise."

631. Defendants, Plaintiff, and Class members are "persons" within the meaning of Mo. Rev. Stat. § 407.010(5).

632. Defendants engaged in "trade" or "commerce" in the State of Missouri within the meaning of Mo. Rev. Stat. § 407.010(7).

633. Defendants' conduct, as described in this Complaint, constitutes both "deceptive" and "unfair" acts or practices in violation of the Missouri MPA.

634. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

635. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

636. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Missouri MPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

637. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

638. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable

consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

639. Defendants knew or should have known that their conduct violated the Missouri MPA.

640. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

641. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

642. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

643. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

644. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

645. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

646. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

647. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

648. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

649. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Mo. Rev. Stat. § 407.025.

COUNT TWENTY THREE – VIOLATION OF THE MONTANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT ("MONTANA UTPCPA"), Mont. Code § 30-14-103, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

650. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

651. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

652. The Montana UTPCPA provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful."

653. Defendants, Plaintiff, and Subclass members are "persons" within the meaning of Mont. Code § 30-14-102(6).

654. Plaintiff and Subclass members are "consumers" within the meaning of Mont. Code § 30-14-102(1).

655. Defendants' conduct related to the marketing of Makena constituted unfair methods of competition and unfair or deceptive acts or practices in violation of the Montana UTPCPA.

656. Plaintiff and Subclass members have suffered an ascertainable loss of money or property as a result of Defendants' use or employment of methods, acts, and practices declared unlawful by the Montana UTPCPA.

657. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

658. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

659. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Montana UTPCPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

660. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

661. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to

create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

662. Defendants knew or should have known that their conduct violated the Montana UTPCPA.

663. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

664. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

665. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

666. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

667. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

668. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

669. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

670. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

671. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

672. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Mont. Code § 30-14-133.

COUNT TWENTY FOUR – VIOLATION OF THE NEBRASKA CONSUMER PROTECTION ACT ("NEBRASKA CPA"), Neb. Rev. Stat. § 59-1602, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

673. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

674. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

675. The Nebraska CPA prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce."

676. Defendants, Plaintiff, and Subclass members are "person[s]" under Neb. Rev. Stat. § 59-1601(1).

677. Defendants' actions as set forth herein occurred in the conduct of trade or commerce as defined under Neb. Rev. Stat. § 59-1601(2).

678. Defendants' conduct, as described in this Complaint, constitutes both "deceptive" and "unfair" acts or practices in violation of the Nebraska CPA.

679. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at

preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

680. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

681. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Nebraska CPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

682. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

683. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

684. Defendants knew or should have known that their conduct violated the Nebraska CPA.

685. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

686. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

687. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

688. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

689. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

690. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that

Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

691. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

692. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

693. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

694. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Neb. Rev. Stat. § 59-1609.

COUNT TWENTY FIVE – VIOLATION OF THE NEVADA DECEPTIVE TRADE PRACTICES ACT ("NEVADA DTPA"), Nev. Rev. Stat. § 598.0903, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

695. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

696. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

697. The Nevada DTPA prohibits deceptive trade practices. The statute provides that a person engages in a "deceptive trade practice" if, in the course of business or occupation, the person: "[k]nowingly makes any other false representation in a transaction"; "[f]ails to disclose a material fact in connection with the sale or lease of goods or services"; and/or "[m]akes an assertion of scientific, clinical or quantifiable fact in an advertisement which would cause a reasonable person to believe that the assertion is true, unless, at the time the assertion is made, the person making it has possession of factually objective scientific, clinical or quantifiable evidence which substantiates the assertion."

698. Defendants' conduct, as described in this Complaint, constitutes "deceptive" acts or practices in violation of the Nevada DTPA.

699. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

700. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

701. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Nevada DTPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

702. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

703. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

704. Defendants knew or should have known that their conduct violated the Nevada DTPA.

705. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

706. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and

expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

707. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

708. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

709. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

710. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

711. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered

them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

712. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

713. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

714. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Nev. Rev. Stat. § 41.600.

COUNT TWENTY SIX – VIOLATION OF THE NEW HAMPSHIRE CONSUMER PROTECTION ACT ("NEW HAMPSHIRE CPA"), N.H. Rev. Stat. Ann. Tit. XXXI § 358-A, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

715. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

716. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

717. The New Hampshire CPA prohibits a person, in the conduct of any trade or commerce, from "using any unfair or deceptive act or practice," including, but not limited to: "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that such person does not have" and "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another."

718. Defendants, Plaintiff, and Subclass members are "persons" under N.H. Rev. Stat. § 358-A:1.

719. Defendants' actions as set forth herein occurred in the conduct of trade or commerce as defined under N.H. Rev. Stat. § 358-A:1.

720. Defendants' conduct, as described in this Complaint, constitutes both "deceptive" and "unfair" acts or practices in violation of the New Hampshire CPA.

721. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

722. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

723. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the New Hampshire CPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

724. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

725. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

726. Defendants knew or should have known that their conduct violated the New Hampshire CPA.

727. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

728. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and

expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

729. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

730. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

731. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

732. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

733. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered

them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

734. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

735. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

736. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to N.H. Rev. Stat. § 358-A:10.

COUNT TWENTY SEVEN – VIOLATION OF THE NEW MEXICO UNFAIR TRADE PRACTICES ACT ("NEW MEXICO UTPA"), N.M. Stat. § 57-12-1, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

737. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

738. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

739. The New Mexico UTPA makes unlawful "a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale . . . of goods or services . . . by a person in the regular course of the person's trade or commerce, that may, tends to or does deceive or mislead any person," including, but not limited to, "failing to state a material fact if doing so deceives or tends to deceive."

740. Defendants, Plaintiff, and Subclass members are "person[s]" under N.M. Stat. § 57-12-2.

741. Defendants' actions as set forth herein occurred in the conduct of trade or commerce as defined under N.M. Stat. § 57-12-2.

742. Defendants' conduct, as described in this Complaint, constitutes a pattern of "false or misleading oral or written statement[s]" in violation of N.M. Stat. § 57-12-2(D).

743. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

744. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

745. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the New Mexico UTPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

746. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

747. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

748. Defendants knew or should have known that their conduct violated the New Mexico UTPA.

749. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

750. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

751. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

752. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

753. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

754. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

755. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer

Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

756. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

757. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

758. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to N.M. Stat. § 57-12-10.

COUNT TWENTY EIGHT – VIOLATION OF THE NEW YORK GENERAL BUSINESS LAW ("NEW YORK GBL"), N.Y. Gen. Bus. Law §§ 349-350
On behalf of Plaintiff and the Consumer Protection Subclass

759. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

760. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

761. The New York GBL makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce."

762. Plaintiff and Class members are "persons" within the meaning of N.Y. Gen. Bus. Law § 349(h).

763. Each Defendant is a "person," "firm," "corporation," or "association" within the meaning of N.Y. Gen. Bus. Law § 349.

764. Defendants' conduct, as described in this Complaint, constitutes deceptive acts in violation of the New York GBL.

765. Defendants' fraudulent marketing of Makena was targeted at patients, providers, and health plans who cover the costs of Makena for their members. These deceptive acts and practices constituted conduct directed at consumers.

766. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

767. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

768. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and

unfair acts prohibited by the New York GBL by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

769. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

770. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

771. Defendants knew or should have known that their conduct violated the New York GBL.

772. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

773. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

774. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would

not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

775. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

776. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

777. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

778. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

779. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

780. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

781. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to N.Y. Gen. Bus. Law § 349.

COUNT TWENTY NINE – VIOLATION OF THE NORTH CAROLINA UNFAIR AND DECEPTIVE TRADE PRACTICES ACT ("NCUDTPA"), N.C. Gen. Stat. § 75-1.1, *et seq.* On behalf of Plaintiff and the Consumer Protection Subclass

782. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

783. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

784. The NCUDTPA broadly prohibits "unfair or deceptive acts or practices in or affecting commerce."

785. Defendants' conduct, as described in this Complaint, constitutes "deceptive acts" in violation of the NCUDTPA.

786. In addition, Defendants' conduct, as described in this Complaint, constitutes "unfair" acts in violation of the NCUDTPA.[81]

787. Defendants engaged in "commerce" within the meaning of N.C. Gen. Stat. § 75-1.1(b).

788. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

789. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

790. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the NCUDTPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

791. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the

[81] *Melton v. Family First Mortg. Corp.*, 576 S.E.2d 365, 368 (2003) ("A practice is unfair [under the NCUDTPA] when it offends established public policy as well as when the practice is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers" and offering a separate definition for "deceptive" practices (internal quotation marks and citations omitted)).

deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

792. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

793. Defendants knew or should have known that their conduct violated the NCUDTPA.

794. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

795. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

796. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

797. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

798. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

799. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

800. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

801. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

802. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

803. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to N.C. Gen. Stat. § 75-16.

COUNT THIRTY – VIOLATION OF THE NORTH DAKOTA CONSUMER FRAUD ACT ("NORTH DAKOTA CFA"), N.D. Cent. Code § 51-15-02, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

804. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

805. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

806. The North Dakota CFA makes unlawful the "act, use, or employment by any person of any deceptive act or practice, fraud, false pretense, false promise, or misrepresentation, with the intent that others rely thereon in connection with the sale or advertisement of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is declared to be an unlawful practice." The statute further provides that the "act, use, or

employment by any person of any act or practice, in connection with the sale or advertisement of any merchandise, which is unconscionable or which causes or is likely to cause substantial injury to a person which is not reasonably avoidable by the injured person and not outweighed by countervailing benefits to consumers or to competition, is declared to be an unlawful practice."

807. Defendants, Plaintiff, and Subclass members are "persons" within the meaning of N.D. Cent. Code § 51-15-02(4).

808. Defendants engaged in the "sale" of "merchandise" within the meaning of N.D. Cent. Code § 51-15-02(3), (5).

809. Defendants' conduct, as described in this Complaint, constitutes "deceptive acts" in violation of the North Dakota CFA.

810. Defendants' conduct, as described in this Complaint, constitutes "unconscionable conduct" in violation of the North Dakota CFA.

811. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

812. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

813. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and

unfair acts prohibited by the North Dakota CFA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

814. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

815. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

816. Defendants knew or should have known that their conduct violated the North Dakota CFA.

817. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

818. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

819. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would

not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

820. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

821. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

822. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

823. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

824. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

825. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

826. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to N.D. Cent. Code § 51-15-09.

COUNT THIRTY ONE– VIOLATION OF THE OHIO CONSUMER SALES PRACTICES ACT ("OHIO CSPA"), Ohio Rev. Code § 1345.01, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

827. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

828. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

829. Defendants are "suppliers" as that term is defined in Ohio Rev. Code § 1345.01(C).

830. Plaintiff and Consumer Protection Subclass members are "consumers" as that term is defined in Ohio Rev. Code § 1345.01(D).

831. The relevant health plan payments for Makena are "consumer transaction[s]" within the meaning of Ohio Rev. Code § 1345.01(A).

832. The Ohio CSPA broadly prohibits "unfair or deceptive act[s] or practice[s] in connection with a consumer transaction." Ohio Rev. Code § 1345.02.

833. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

834. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

835. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Ohio CSPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

836. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing

preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

837. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

838. Defendants knew or should have known that their conduct violated the Ohio CSPA.

839. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

840. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

841. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

842. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to

effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

843. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

844. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

845. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

846. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that

Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

847. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

848. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Ohio Rev. Code § 1345.09, *et seq.*

COUNT THIRTY TWO – VIOLATION OF THE OHIO DECEPTIVE TRADE PRACTICES ACT ("OHIO DTPA"), Ohio Rev. Code § 4165, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

849. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

850. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

851. The Ohio DTPA prohibits "deceptive trade practices," which includes: "[r]epresent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have" and "[r]epresent[ing] that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another."

852. Defendants, Plaintiff, and Subclass members are "persons" within the meaning of Ohio Rev. Code § 4165.01(D).

853. Defendants' conduct with respect to the marketing of Makena, as described in this Complaint, constitutes deceptive trade practices in violation of the Ohio DTPA.

854. In violation of the Ohio DTPA, Defendants employed unfair, unlawful and deceptive acts or practices, fraud, false pretense, misrepresentations, and/or concealment, suppression or omission of material facts with the intent that their target audience of patients, prescribers and third-party payors rely on such misrepresentation, concealment, suppression or omission in connection with the sale of Makena. Defendants knowingly misrepresented, concealed, suppressed and/or omitted material facts regarding Makena which directly caused harm to Plaintiff and members of the Consumer Protection Subclass.

855. Defendants knew that Makena was ineffective at treating preterm birth for years and yet failed to disclose and actively concealed that fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

856. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

857. Defendants continued efforts to create the impression that Makena is effective at treating preterm birth despite knowledge to the contrary constituted false and/or misleading statements about Makena in violation of the Ohio DTPA.

858. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the

deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

859. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in patients, prescribers and third-party payors which were the target audience of Defendants false and/or misleading statements, and were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

860. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

861. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

862. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that

Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

863. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

864. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

865. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss proximately caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

866. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

867. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual damages and reasonable attorneys' fees, pursuant to Ohio Rev. Code § 4165.03.

COUNT THIRTY THREE – VIOLATION OF THE OREGON UNLAWFUL TRADE PRACTICES ACT ("OREGON UTPA"), Or. Rev. Stat. § 646.605, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

868. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

869. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

870. The Oregon UTPA prohibits a person from, in the course of the person's business, engaging "in any other unfair or deceptive conduct in trade or commerce."

871. Each Defendant is a person within the meaning of Or. Rev. Stat. § 646.605(4).

872. Each Makena prescription is a "good" obtained primarily for personal family or household purposes within the meaning of Or. Rev. Stat. § 646.605(6).

873. Defendants' conduct, as described in this Complaint, constitutes "unfair or deceptive conduct."

874. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

875. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

876. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Oregon UTPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

877. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

878. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

879. Defendants knew or should have known that their conduct violated the Oregon UTPA.

880. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

881. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and

expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

882. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

883. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

884. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

885. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

886. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered

them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

887. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

888. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

889. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Or. Rev. Stat. §§ 646.632, 646.636, 646.638(1).

COUNT THIRTY FOUR – VIOLATION OF THE RHODE ISLAND DECEPTIVE TRADE PRACTICES ACT ("RHODE ISLAND DTPA"), R.I. Gen. Laws § 6-13.1-1, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

890. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

891. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

892. The Rhode Island DTPA provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful."

893. Unfair methods of competition and unfair or deceptive acts and practices includes: "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have;" "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;" "[e]ngaging in any other conduct that similarly creates a likelihood of confusion or of misunderstanding;" "[e]ngaging in any act or practice that is unfair or deceptive to the consumer;" and "[u]sing any other methods, acts, or practices that mislead or deceive members of the public in a material respect."

894. Defendants, Plaintiff, and Subclass members are "persons" within the meaning of R.I. Gen. Laws § 6-13.1-1(3).

895. Defendants' conduct with respect to the marketing of Makena, as described in this Complaint, constitutes unfair methods of competition and unfair or deceptive acts and practices in violation of the Rhode Island DTPA.

896. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

897. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

898. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Rhode Island DTPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

899. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

900. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

901. Defendants knew or should have known that their conduct violated the Rhode Island DTPA.

902. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

903. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

904. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

905. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

906. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

907. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

908. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

909. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

910. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

911. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and

proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to R.I. Gen. Laws § 6-13.1-5.2.

COUNT THIRTY FIVE – VIOLATION OF THE SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT ("SOUTH CAROLINA UTPA"), S.C. Code Ann. § 39-5-10, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

912. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

913. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

914. The South Carolina UTPA prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce."

915. Each Defendant is a "person" under S.C. Code Ann. § 39-5-10.

916. Defendants' conduct, as described in this Complaint, constitutes "deceptive acts" in violation of the South Carolina UTPA.

917. In addition, Defendants' conduct, as described in this Complaint, constitutes "unfair" acts in violation of the South Carolina UTPA.

918. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

919. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

920. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the South Carolina UTPA by engaging in acts or practices which are otherwise unfair, misleading, false, or deceptive to the consumer.

921. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

922. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

923. Defendants knew or should have known that their conduct violated the South Carolina UTPA.

924. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

925. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and

expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

926. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

927. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

928. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

929. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

930. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered

them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

931. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

932. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

933. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to S.C. Code Ann. § 39-5-140(a).

COUNT THIRTY SIX – VIOLATION OF THE SOUTH DAKOTA DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION LAW ("SOUTH DAKOTA DTPCPL"), S.D. Codified Laws § 37-24, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

934. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

935. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

936. The South Dakota DTPCPL provides that "[i]t is a deceptive act or practice for any person to . . . [k]nowingly act, use, or employ any deceptive act or practice, fraud, false pretense, false promises, or misrepresentation or to conceal, suppress, or omit any material fact in connection with the sale or advertisement of any merchandise, regardless of whether any person has in fact been misled, deceived, or damaged thereby."

937. Defendants, Plaintiff, and Subclass members are "persons" within the meaning of S.D. Codified Laws § 37-24-1(8).

938. Defendants conduct with respect to the marketing of Makena, as described in this Complaint, constitutes a deceptive act or practice in violation of the South Dakota DTPCPL.

939. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

940. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

941. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and

unfair acts prohibited by the South Dakota DTPCPL by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

942. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

943. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

944. Defendants knew or should have known that their conduct violated the South Dakota DTPCPL.

945. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

946. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

947. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would

not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

948. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

949. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

950. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

951. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

952. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

953. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

954. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to S.D. Codified Laws § 37-24-31.

COUNT THIRTY SEVEN – VIOLATION OF THE TENNESSEE CONSUMER PROTECTION ACT ("TENNESSEE CPA"), Tenn. Code Ann. § 47-18-101, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

955. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

956. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

957. The Tennessee CPA prohibits "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce," including, but not limited to, "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that

they do not have or that a person has a sponsorship approval, status, affiliation or connection that such person does not have" and "[r]epresenting that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another."

958. Plaintiff and Subclass members are "persons" within the meaning of Tenn. Code Ann. § 47-18-103(2).

959. Each Defendant is a "person" within the meaning of Tenn. Code Ann. § 47-18-103(2).

960. Each Defendant's conduct complained of herein affected "trade," "commerce," or "consumer transactions" within the meaning of Tenn. Code Ann. § 47-18-103(19).

961. Defendants' conduct, as described in this Complaint, constitutes "deceptive acts" in violation of the Tennessee CPA.

962. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

963. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

964. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and

unfair acts prohibited by the Tennessee CPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

965. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

966. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

967. Defendants knew or should have known that their conduct violated the Tennessee CPA.

968. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

969. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

970. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would

not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

971. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

972. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

973. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

974. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

975. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

976. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

977. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Tenn. Code Ann. § 47-18-109(a).

COUNT THIRTY EIGHT – VIOLATION OF THE UTAH CONSUMER SALES PRACTICES ACT ("UTAH CSPA"), Utah Code § 13-11-1, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

978. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

979. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

980. The Utah CSPA makes unlawful any "deceptive act or practice by a supplier in connection with a consumer transaction," including, but not limited to, "indicat[ing] that the subject of a consumer transaction has sponsorship, approval, performance characteristics,

accessories, uses, or benefits, if it has not;" "indicat[ing] that the subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not;" and "indicat[ing] that the subject of a consumer transaction has been supplied in accordance with a previous representation, if it has not."

981. "An unconscionable act or practice by a supplier in connection with a consumer transaction" also violates the Utah CSPA.

982. As alleged in this Complaint, Defendants have engaged in deceptive acts in violation of the Utah CSPA.

983. They have also engaged in unconscionable actions in violation of the Utah CSPA. Defendants knew, or had reason to know, that health plans would rely on their representations as to the efficacy of Makena, and they knew that these representations were false.

984. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

985. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

986. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and

unfair acts prohibited by the Utah CSPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

987. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

988. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

989. Defendants knew or should have known that their conduct violated the Utah CSPA.

990. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

991. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

992. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would

not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

993. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

994. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

995. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

996. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations

and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

997. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

998. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

999. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Utah Code § 13-11-4.

COUNT THIRTY NINE – VIOLATION OF THE VERMONT CONSUMER FRAUD ACT ("VERMONT CFA"), Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

1000. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

1001. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

1002. The Vermont CFA makes unlawful "[u]nfair methods of competition in commerce and unfair or deceptive acts or practices in commerce."

1003. Defendants were sellers within the meaning of Vt. Stat. Ann. tit. 9, § 2451(a)(c).

1004. Defendants' conduct, as described in this Complaint, constitutes "deceptive acts" in violation of the Vermont CFA.

1005. Defendants' conduct, as described in this Complaint, constitutes "unfair acts" in violation of the Vermont CFA.

1006. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

1007. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

1008. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Vermont CFA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

1009. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

1010. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

1011. Defendants knew or should have known that their conduct violated the Vermont CFA.

1012. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

1013. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

1014. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

1015. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that

Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

1016. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

1017. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

1018. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

1019. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on

their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

1020. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

1021. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Vt. Stat. Ann. tit. 9, § 2461(b).

COUNT FORTY – VIOLATION OF THE VIRGINIA CONSUMER PROTECTION ACT ("VIRGINIA CPA"), Va. Code Ann. § 59.1-196, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

1022. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

1023. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

1024. Virginia CPA lists prohibited "fraudulent acts or practices" which include: "[m]isrepresenting that goods or services have certain quantities, characteristics, ingredients, uses, or benefits;" "[m]isrepresenting that goods or services are of a particular standard, quality, grade, style, or model;" and "[u]sing any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction."

1025. Each Defendant is a "supplier" under Va. Code Ann. § 59.1-198.

1026. The relevant purchases of Makena were "consumer transactions" within the meaning of Va. Code Ann. § 59.1-198.

1027. Defendants' conduct, as described in this Complaint, constitutes "fraudulent acts" in violation of the Virginia CPA.

1028. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

1029. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

1030. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Virginia CPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

1031. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

1032. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable

consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

1033. Defendants knew or should have known that their conduct violated the Virginia CPA.

1034. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

1035. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

1036. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

1037. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

1038. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

1039. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

1040. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

1041. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

1042. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

1043. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Va. Code Ann. § 59.1-204..

COUNT FORTY ONE – VIOLATION OF THE WEST VIRGINIA CONSUMER CREDIT AND PROTECTION ACT ("WEST VIRGINIA CCPA"), W. Va. Code § 46A-6-101, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

1044. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

1045. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

1046. The West Virginia CCPA provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

1047. "Unfair methods of competition and unfair or deceptive acts or practices" under the West Virginia CCPA includes, but is not limited to: "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;" "[r]epresenting that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model if they are of another;" "[e]ngaging in any other conduct which similarly creates a likelihood of confusion or of misunderstanding;" and "[t]he act, use or employment by any person of any deception, fraud, false pretense, false

promise or misrepresentation, or the concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any goods or services, whether or not any person has in fact been misled, deceived or damaged thereby."

1048. Defendants' conduct with respect to the marketing of Makena, as described in this complaint, constitutes unfair methods of competition and unfair or deceptive acts or practices in violation of the West Virginia CCPA.

1049. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

1050. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

1051. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the West Virginia CCPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

1052. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing

preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

1053. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

1054. Defendants knew or should have known that their conduct violated the West Virginia CCPA.

1055. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

1056. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

1057. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

1058. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to

effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

1059. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

1060. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

1061. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

1062. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that

Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

1063. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

1064. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to W. Va. Code § 46A-6-106.

COUNT FORTY TWO – VIOLATION OF THE WISCONSIN DECEPTIVE TRADE PRACTICES ACT ("WISCONSIN DTPA"), Wis. Stat. § 100.18, *et seq.*
On behalf of Plaintiff and the Consumer Protection Subclass

1065. Plaintiff hereby incorporates by reference the preceding paragraphs as if they were fully set forth herein.

1066. Plaintiff brings this cause of action on its own behalf and on behalf of the members of the Consumer Protection Subclass.

1067. The Wisconsin DTPA prohibits a "representation or statement of fact which is untrue, deceptive or misleading."

1068. Each Defendant is a "person, firm, corporation or association" within the meaning of Wis. Stat. § 100.18(1).

1069. Plaintiff and Class members are members of "the public" within the meaning of Wis. Stat. § 100.18(1).

1070. Defendants' conduct, as described in this Complaint, constitutes "representation[s] or statement[s] of fact which [were] untrue, deceptive or misleading" in violation of the Wisconsin DTPA.

1071. Defendants knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact. Even after receiving definitive confirmation via the results of the PROLONG study that Makena is no better than a placebo at preventing preterm birth, Defendants redoubled their efforts to convince prescribers, patients, and third-party payors that Makena was an effective drug that they should include on their formularies and pay for.

1072. Moreover, Defendants engaged in efforts to attempt to prevent, or at least delay, the FDA from removing Makena from the market in order to continue profiting off of sales of Makena at the expense of Plaintiff and Consumer Protection Subclass members.

1073. By willfully failing to disclose and actively concealing the fact that Makena is ineffective at preventing preterm birth, Defendants engaged in deceptive business practices and unfair acts prohibited by the Wisconsin DTPA by engaging in acts or practices which are otherwise unfair, misleading, false or deceptive to the consumer.

1074. In the course of Defendants' business, they willfully failed to disclose and actively concealed the truth about Makena's ineffectiveness. Defendant compounded the deception by repeatedly asserting that Makena was a safe and effective means of preventing preterm birth and by seeking to prevent and/or delay the withdrawal of Makena from the market for as long as possible.

1075. Defendants' unfair or deceptive acts or practices, including these concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead, tended to

create a false impression in consumers, were likely to and did in fact deceive reasonable consumers, including the members of the Consumer Protection Subclass, about the true efficacy of Makena.

1076. Defendants knew or should have known that their conduct violated the Wisconsin DTPA.

1077. To protect their profits, Defendant concealed the ineffectiveness of Makena at treating preterm birth and allowed unsuspecting third-party payors to pay for this worthless drug.

1078. Defendants intended that Plaintiff and members of the Consumer Protection Subclass would, in the course of their decision to include Makena on their formularies and expend money paying for doses of Makena, reasonably rely upon material misrepresentations and/or omissions concerning the efficacy of Makena in preventing preterm birth.

1079. Information regarding the efficacy of Makena in preventing preterm birth was material to Plaintiff and Consumer Protection Subclass members in that Plaintiff and Consumer Protection Subclass members would not have included Makena on their formularies and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members if Defendants had not made misrepresentations and/or omissions regarding the efficacy of Makena and/or had disclosed that Makena was ineffective at preventing preterm birth.

1080. Defendants misrepresented Makena's effectiveness at preventing preterm birth and failed to disclose and omitted the information that it knew about Makena's inability to effectively prevent preterm birth. Defendants' misrepresentations and/or omissions caused Plaintiff and members of the Consumer Protection Subclass to be unaware of the fact that Makena was not effective at preventing preterm birth at the time they included Makena on their formularies and/or paid for doses of Makena prescribed to their plan members.

1081. Defendants' deceptive conduct was likely to deceive a reasonable person and did, in fact, deceive reasonable third-party payors including Plaintiff and members of the Consumer Protection Subclass.

1082. Plaintiff and members of the Consumer Protection Subclass reasonably relied upon Defendants' misrepresentations and/or omissions. They had no way of knowing that Defendants' representations were false and misleading. Plaintiff and members of the Consumer Protection Subclass did not (and could not) unravel Defendants' deception on their own.

1083. The facts concealed and omitted by Defendants from Plaintiff and members of the Consumer Protection Subclass are material in that a reasonable person would have considered them to be important in deciding whether to include Makena on their formularies and/or pay for doses of Makena prescribed to their plan members. Plaintiff and members of the Consumer Protection Subclass would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, Makena prescriptions prescribed to their plan members if Defendants had not engaged in material misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth.

1084. Plaintiff and members of the Consumer Protection Subclass suffered ascertainable loss caused by Defendants' failure to disclose material information. Had Defendants not made misrepresentations and/or omissions regarding the efficacy of Makena and/or disclosed that Makena was ineffective at preventing preterm birth they would not have included Makena on their formularies during the Class Period and would not have paid for, or would have paid less for, prescriptions of Makena prescribed to their plan members.

1085. Defendant knew that Makena was ineffective at treating preterm birth for years and failed to disclose and actively concealed this fact.

1086. As a result of Defendants' wrongful conduct, Consumer Protection Subclass Members have been damaged in an amount to be proven at trial. Plaintiff will seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, court costs, and reasonable attorneys' fees, pursuant to Wis. Stat. § 100.18(11)(b)(2).

VIII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the Classes, respectfully requests that the Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) and declare Plaintiff as representative of the Classes and Plaintiff's counsel as Class Counsel for the Classes;

B. Award the Classes compensatory, statutory, treble and punitive damages in an amount to be determined at trial, plus interest in accordance with law;

C. Award Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

D. Award such further and additional relief as is necessary to correct for the harm caused by the Defendants' unlawful conduct, as the Court may deem just and proper under the circumstances.

IX. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Cleveland Bakers and Teamsters Health & Welfare Fund, on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

Dated: October 27, 2023

Respectfully submitted,

/s/ Thomas M. Sobol

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